EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7400GB448230921	7400AU08F	2023-09-21	2025-11-15

This is to certify that the quality system of

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
SRN: DE-MF-000005504

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Digitally signed by Moraru Grigore
Date: 2024.08.16 15:36:23 EEST
Reason: MoldSign Signature
Location: Moldova

Place and date
Hamburg, 2023-09-21

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Preceding certificate

Certificate no.	Issue date	Identification of changes
7400GB448220414	2022-04-14	Exension by class IIa + Intended purpose class IIb, WO-009751, WO-010862

Sites covered by this certificate

Aesculap AG, Am Aesculap-Platz, 78532 Tuttlingen, Germany

Products covered by this certificate

Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Class	Medical devices/groups of medical devices
MDN 1208	Ir	Non-active non-implantable instruments

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0202	Z120111	Instruments for operative microscopy
MDN 1208	K010201	Minimally invasive surgery surgical instruments, single-use
MDN 1208	L031205	Orthopaedic surgery trocar, reusable
MDN 1208	L070702	Cardiac dilators and retractors, reusable
MDN 1208	L091099	Osteosynthesis instruments, reusable - other
MDN 1208	L091102	Orthopaedic prostheses reamers and burs, reusable
MDN 1208	L091199	Orthopaedic prosthetics instruments, reusable - other
MDN 1208	L110501	Vertebral surgery spreaders and retractors, reusable
MDN 1208	P091203	Bone fixation wires
MDN 1208	P091303	Orthopaedic implant drill bits, single-use
MDN 1208	P091399	Orthopaedic implant instruments, single-use - other
MDN 1208	V0199	Cutting devices, single-use - other
MDN 1208	Z120114	Surgical navigation instruments
MDN 1208	Z120190	Various instruments for general and multidisciplinary surgery
MDN 1208	Z120207	Genitourinary endoscopy instruments
MDN 1208	Z120209	Neuroendoscopy instruments
MDN 1208	Z120211	Orthopaedic endoscopy instruments
MDN 1208	Z120290	Various instruments for endoscopy and mini-invasive surgery
MDN 1208	Z121305	Motorised orthopaedic surgery system instruments

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090701	Spinal fusion systems

Intended purpose

TA012095: PEEK Cages are used as follows:

- CeSPACE® PEEK: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® PEEK: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® PEEK: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA012353: Titanium cages are used as follows:

- CeSPACE® Ti: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® Ti PLIF: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® Ti TLIF: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® Ti: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA013625: PLASMAPORE XP® Cages are used as follows:

- CeSPACE® XP: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® XP: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- TSPACE® XP: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

TA015914: 3D Cages are used as follows:

- CeSPACE® 3D: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental
- PROSPACE® 3D: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental
- PROSPACE® 3D Oblique: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental
- TSPACE® 3D: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA009693: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA011187: The S4 Spinal System Implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. They comprise: ■ Mono/polyaxial screws ■ Rods ■ Hook ■ Cross connector ■ Rod connectors – parallel, axial and lateral offset ■ appropriate fixation elements. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA011700: The ABC implants are used exclusively for anterior monosegmental and multisegmental stabilization of the cervical spine in the region from C2 to Th1.

TA012865: The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The S4 Spinal System – augmentation screw can be fixed with bone cement to increase anchoring stability. In this case, the injection cannula is inserted in the S4 Spinal System – augmentation screw for application of the bone cement. The S4 Spinal System - augmentation screw comprises: ■ S4 Monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ S4 Element monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ Cement injection cannula (sterile), see TA013132 ■ for percutaneous application with S4 Element monoaxial/polyaxial screws (augmentation screws): S4 Element Augmentation instruments, see TA014315.
Note: There are special S4 instruments provided for the implantation of these system components and for the augmentation, distraction, compression, and reduction of the lumbar and thoracic spine.

TA013366: The Quintex cervical plating system is used for the anterior monosegmental and multisegmental stabilization of the cervical spine.

TA013579: Note: The S4 Spinal System – in sterile condition is addressed in general in the operating instructions for the S4 Spinal System – Lumbar/Deformity TA011187. This information on the sterile-packaged S4 implants supplements the respective information in the instructions for use of the S4 Spinal System – Lumbar/Deformity. The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The parallel (closed and open) and axial rod connectors are connected to S4 Spinal System rods in order to connect a rod parallel or in a line with another rod. The lateral offset connectors are connected to the S4 Spinal System rods in order to place a screw offset. The rod connectors thus extend the rod to the adjacent spinal column segments. The S4 Spinal System – sterile-packaged comprises: ■ Rod connector – parallel (closed and open), axial and lateral offset connectors.

Note: Special S4 instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine.

TA014887: The Ennovate Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar, thoracic and sacral spine.

TA015555: The ArcadiusXP L Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach. The system contains: ■ Cages in different heights, angles and footprints ■ Bone screws in different lengths.

TA015777: The Ennovate Cervical Spinal System implants are used for the posterior monosegmental and multisegmental stabilization of the occipitocervical junction and of the cervical and upper thoracic spine. The system consists of: Occiput plates and screws, Rods, Polyaxial screws, Bone screws, Set screws, Hook, Cross connectors (head-to-head cross connectors, rod-to-rod cross connectors), Other connectors, Laminoplasty plate. The Ennovate Cervical laminoplasty plate is intended for use in the cervical spine (C3-C6) after a unilateral laminoplasty has been performed. It is fixated to the lamina with the SecureSpan screws. Surgically installed implants serve to support the normal healing process. They are not supposed to replace normal body structures or to support permanent loads that occur in cases where healing does not occur. The laminoplasty plate should be used with a stabilization block (by e.g. a bone graft). Appropriate implant components from Ennovate Spinal System (e.g. rods) can also be used. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the thoracolumbar spine.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090703	Implantable vertebral stabilisation or fixation systems

Intended purpose

TA018000: The ArcadiusXP C spinal system is intended to be used as an intervertebral body fusion cage as a standalone system used with two bone screws. It is inserted between the vertebral bodies into the disc space from C2 to T1 in skeletally mature patients.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090803	Hip prostheses acetabular components

Intended purpose

TA013800: The implant is used: ■ As a component of a human hip endoprosthesis: Hip endoprosthesis cup, consisting of outer cup Plasmafit® Poly or Plasmafit® Plus, possibly central screw plug, possibly anchoring screws and modular Plasmafit® inserts (standard, asymmetrical or with shoulder) ■ In combination with Aesculap hip endoprosthesis components ■ In combination with implant components explicitly approved by Aesculap ■ For implantation without bone cement.
Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090880	Hip prostheses - accessories

Intended purpose

TA008056: The Centralizer is used as an additional guide when using cemented Aesculap endoprosthesis stems. It acts as a guide for the distal tip of the prosthesis when inserting the stem into the bone cement. If the correct size has been selected, the Centralizer guarantees a closed and uniform cement socket.
Different outer diameters are available for centralizers; they are marked on the packaging. The selection of the correct centralizer depends on the Aesculap hip implant stem used or the Aesculap knee implant component used, and the operative preparation and size of the medullary cavity. Observe the instructions for use for the Aesculap endoprosthesis components used.
The Centralizer is used with Aesculap Endoprosthesis Centrament, Bicontact, Excia, SLA, Vega and Columbus.

TA009897: The anchoring screws are used in combination with Aesculap acetabular implants. They are used to increase stability in the event of insufficient primary stability in Plasmacup® and Plasmafit® press fit cups and to secure the Aesculap reconstruction cup and the acetabular Structan® Augment in the bone. The 6.5 mm anchoring screws may only be used as explained below: ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components ■ in the listed implant systems according to their color coding. Color coding of anchoring screws / Permissible use - Yellow oxide layer Plasmacup® and Aesculap recon ring - Blue oxide layer Plasmafit® and acetabular Structan® Augment. Anchoring screws are available in different lengths. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA012315: For use with a cemented Trilliance or CoreHip hip endoprosthesis stem.
See instructions for use of Trilliance-/CoreHip hip endoprosthesis stems.

TA012526: The implant is used: ■ as a component part of a human hip endoprosthesis: Locking screw ■ in combination with Aesculap hip endoprosthesis stems with locking holes ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components.
The locking screws are intended for the fixation of above-mentioned implant components that allow distal locking. The operating surgeon decides, depending on the indication, if and to what degree implant locking is necessary. Note: The options of patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA013723: The implant is used: ■ as a component of a human hip endoprosthesis: augmentation implant for filling of acetabular bone defects ■ in combination with Aesculap hip endoprosthesis components: Plasmafit, Plasmafit Revison, Plasmacup, cemented PE cups ■ in combination with implant components explicitly approved by Aesculap ■ in combination with hip endoprosthesis cups with the same nominal diameter, or one that is a maximum of 4 mm smaller/larger ■ in combination with bone cement at the interface to the hip cup.
The anchoring screws must only ever be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.
Yellow oxide layer - Plasmacup; Blue oxide layer - Plasmafit Plus, Plasmafit Revision, Structan acetabulum augmentation implant; Pink oxide layer - Structan acetabulum augmentation implant.
Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

TA015599: The 4.5 mm anchoring screws are used in conjunction with Aesculap acetabulum implants. It serves to secure the Structan® acetabulum augmentation in the bone. The 4.5 mm anchoring screws may only be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding.
Pink oxide layer - Structan® acetabulum augmentation.
The anchoring screws are available in various lengths.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090908	Knee prostheses spacers

Intended purpose

TA016100: The implant is used:

■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants

■ in combination with implant components explicitly approved by Aesculap

– univation® X

– Columbus®

– e.motion®

– VEGA System®

– EnduRo

■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems

■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	P090980	Knee prostheses - accessories

Intended purpose

TA016100: The implant is used:

■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants

■ in combination with implant components explicitly approved by Aesculap

– univation® X

– Columbus®

– e.motion®

– VEGA System®

– EnduRo

■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems

■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components.

Note: The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems

Category	EMDN code	Medical devices/groups of medical devices
MDN 1104	H030102	Singular clips for open surgery

Intended purpose

TA013486: The DS titanium ligation-clips are used for the ligation of vessels and hollow organs and for marking anatomical structures

Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

Certificate no.: 7400GB448230921
Place and date: Hamburg, 2023-09-21

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDA 0312	Other active non-implantable surgical devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1208	Non-active non-implantable instruments

B|BRAUN

Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2015
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2016
(Certificate No.: Q5 17 03 10066 408)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products (TÜV EC-Certificate No.: G1 14 05 10066 366 or MEDCERT EC-Certificate No.: 7400GB410170801).

By labeling the products

Aesculap Product Groups
as per attached list

with the CE mark

we, **AESCULAP AG** confirm,
that we follow the essential requirements
according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2019-06-11

AESCULAP AG

i. V.
Rainer Siglinger
Regulatory Affairs

i. A.
Denise Hermle
Regulatory Affairs

B|BRAUN

Attachment to Declaration of 2019-06-11

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint implants (hip,knee)
Surgical Implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation systems
Special suture-sets
Implants for replacement of connective tissue
Tissue adhesives
Vascular prostheses and accessories
Local haemostatics
Other surgical accessories

Str. Paul Chinezu nr. 4, Timisoara, Romania
E-mail: office@besttrados.ro
VALERICA PĂTRU
Tel.: +40 722 555 883

Traducere din limba engleză

B. BRAUN

Declaraţie

Organismul pentru certificare al TUV Management Service GmbH şi TUV Product Service GmbH confirmă că subscrisa

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANIA

a stabilit şi menţine un system de calitate în conformitate cu

ISO 9001: 2015
(Nr. de înregistrare certificat: 12 100 21724 TMS)
EN ISO 13485: 2016
(Certificat nr .: Q5 17 03 10066 408)
pentru următorul domeniu
Dezvoltarea, producerea și distribuția de implanturi, instrumente, recipiente, dispozitive, materiale pentru suturi, adezivi pentru țesuturi și seturi de proceduri.
Mai mult, am implementat procedura de evaluare a conformității
conform anexei II, clauza 3 din Directiva 93/42 / CEE privind dispozitivele medicale din 14 iunie 1993
pentru dispozitive medicale (TUV EC Certificat nr.: Gl 14 05 10066 366 sau MEDCERT EC - Certificat nr.: 7400GB410170801).
Prin etichetarea produselor
Grupuri de produse AESCULAP
ca pe lista atașată
cu marca CE
Subscrisa, AESCULAP AG confirmăm că
respectăm cerințele esențiale
în conformitate cu Directiva MDD 93/42 / CEE Anexa I.

TUTTLINGEN, 11.06.2019
AESCULAP AG

Rainer Siglinger
Afaceri de reglementare
/semnătură indescifrabilă/

Denise Hermle,
Afaceri de reglementare
/semnătură indescifrabilă/

Anexa la Declaraţia din 11.06.2019

Grup de produse AESCULAP
Instrumente chirurgicale, de diagnostic și dentare
Implanturi articulaţii (șold, genunchi)
Implanturi chirurgicale
Implanturi pentru osteosinteză
Implanturi vasculare neurochirurgicale
Produse pentru ligatură
Sisteme motorii
Dispozitive de chirurgie de înaltă frecvență
Sisteme endoscopice
Sisteme de navigație
Seturi speciale de sutură
Implanturi pentru înlocuirea țesutului conjunctiv
Adezivi pentru țesuturi
Proteze vasculare și accesorii
Hemostatica locală
Alte accesorii chirurgicale

Subsemnata **VALERICA PĂTRU,** traducător autorizat de Ministerul Justiţiei pe limbile: FRANCEZĂ, ENGLEZĂ şi ITALIANĂ cu autorizaţia nr. 17602, certific exactitatea traducerii în limba ROMÂNĂ cu textul înscrisului original în limba ENGLEZĂ care mi-a fost prezentat.

Traducător autorizat,
Valerica Pătru
(17602)

Ministerul Justiției
VALERICA PĂTRU
Traducător interpret autorizat
Engleză, Franceză, Italiană
Autorizația nr. 17602

Aesculap AG
Research and Development

Postfach 40
78501 Tuttlingen

Germany

Contact: Dr.-Ing. Thomas Weik

Fon: +49 7461 95-2539

E-mail: thomas.weik@aesculap.de
Internet: http://www.bbraun.com

Date: October 09, 2018

Magnetic Resonance Imaging of Aesculap Implants

The implants of Aesculap are manufactured out of non ferromagnetic metallic materials like cobalt-chromium-alloys, titanium and titanium-alloys, and stainless steel. Further non metallic materials like ultra-high molecular weight polyethylene, polyether ether ketone, and alumina ceramic as well as mixed oxide ceramic are used.

As described in the literature most of the implants and materials evaluated in the MRI environment do not show an additional hazard under the test conditions chosen. A number of investigations [1-5] demonstrated the safety of implants up to a magnetic field of 3 Tesla. Image artefacts can compromise the quality of the examination.

However, in certain instances, due to the shape and length of singular implants, MRI-related heating due to resonance effects may be a problem (for example external fixation systems) [1,5]. Elongated implants with a dimension of about 25 cm at 1.5 Tesla and about 12 cm at 3 Tesla have been described as critical with regard to a possible heating [6].

We conducted several scientifically valid tests on the interaction of Aesculap implants with the magnetic field of MRI environment. The implants passed the criterion for magnetically induced displacement force, magnetically induced torque and RF induced heating under the specific test condition in the environment of a 1.5 Tesla and a 3 Tesla magnetic resonance tomograph.

Stainless steel used in some trauma devices may exhibit small magnetic interaction and heating in the MRI environment.

Although studies indicate that the MRI procedure up to a field strength of 3 Tesla has minimal effects on most implant devices, it should be moreover noted, that different types and generations of MRI equipment are applied. There are almost innumerable combinations of different implant components possible. Investigations of all combinations and different length of the implants are not available.

To date there are no incidents during the MRI investigation of patients with an Aesculap implant known. However a universally valid declaration regarding the interaction of Aesculap implants with any specific MRI unit under consideration of the individual setting applied cannot be made.

In principle it is recommended to reduce possible risks by using low field strength with low HF – energy and larger wave length. During imaging sequences with low specific absorption rate (SAR) have to be preferred.

Please contact us in case of questions.

Aesculap AG

i. V.

Dr. Thomas Weik
Senior Manager R&D
Material-Scientific & Regulatory Support for Pre-Development

i. V.

Dr. Ina Wüstefeld
Director Medical Scientific Affairs

References

1. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2010 Edition, F.G. Shellock, Biomedical Research Publishing Group Los Angeles, CA

2. "MR Procedures and Biomedical Implants, Materials, and Devices: 1993 Update", F.G Shellock, S. Morisoli, E. Kanal, Radiology, 1993, 189, pp. 587-599

3. "Biomedical Implants and Devices: Assessment of Magnetic Field Interactions with a 3.0 Tesla MR system", F. G. Shellock, Journal of Magnetic Resonance Imaging 2002, 16:721-732

4. "High Field Strength MR Imaging and metallic Biomedical Implants: an in Vitro Evaluation of Deflection Forces and Temperature Changes Induced in Large Prostheses", F.G. Shellock, J. Crues, Radiology 1987, 165 (P): 150

5. "3.0-Tesla MR Safety Information for Implants and Devices," available at http:www.mrisafety.com, under the "Safety Information" tab.

6. "MR Heating Tests of MR Critical Implants", Guest Editorial W. Kainz, Journal of Magnetic Resonance Imaging, 26:450-451, 2007

Aesculap AG
Research and Development (Cercetare și Dezvoltare)

Postfach 40
78501 Tuttlingen

Germania

Contact: Dr.- Ing. Thomas Weik

Tel: +49 7461 95-2539

E-mail: thomas.weik@aesculap.de
Internet: http://www.bbraun.com

Data: 9 octombrie 2018

Imagistica prin rezonanță magnetică în cazul implanturilor Aesculap

Implanturile Aesculap sunt fabricate din materiale metalice non-feromagnetice cum ar fi aliajele cu cobalt-crom, titanul și aliajele cu titan, precum și oțelul inoxidabil. Se folosesc și alte materiale nemetalice, cum ar fi polietilena cu masă moleculară foarte ridicată, polieteretercetona (polimer PEEK) și materialul ceramic alumină, precum și materiale ceramice mixte.

Așa cum este descris în literatura de specialitate, majoritatea implanturilor și materialelor evaluate în mediul IRM nu indică un pericol suplimentar în condițiile de testare alese. În cadrul unor studii [1-5] s-a demonstrat siguranța implanturilor până la câmpul magnetic de 3 Tesla. Defectele de reprezentare vizuală pot compromite calitatea examinării.

Cu toate acestea, în anumite cazuri, din cauza formei și lungimii implanturilor individuale, căldura generată în mediul IRM ca urmare a efectelor rezonanței poate fi o problemă (de exemplu, sisteme cu fixare externă) [1,5]. Implanturile alungite cu o dimensiune de aprox. 25 cm la 1,5 Tesla și aprox. 12 cm la 3 Tesla au fost descrise ca prezentând o importanță critică în ceea ce privește o posibilă încălzire [6].

Am desfășurat mai multe teste valabile din punct de vedere științific cu privire la interacțiunea implanturilor Aesculap cu câmpul magnetic al mediului IRM. Implanturile au îndeplinit criteriul pentru forța de deplasare indusă magnetic, cuplul indus magnetic și căldura indusă de forța rezonanței în condiții specifice de testare în mediul unui tomograf cu o rezonanță magnetică de 1,5 Tesla și de 3 Tesla.

Oțelul inoxidabil folosit în unele dispozitive prevăzute în situații de traumă poate prezenta o interacțiune magnetică și căldură la niveluri reduse în mediul IRM.

Deși studiile indică faptul că procedura IRM, până la o forță a câmpului de 3 Tesla, are efecte minime asupra majorității implanturilor, trebuie precizat în plus faptul că sunt aplicate diferite tipuri și generații de echipamente IRM. Există o varietate aproape nelimitată de combinații de diferite componente de implant posibile. Nu există studii asupra tuturor combinațiilor și diferitelor lungimi de implanturi.

Până la această dată, nu au existat incidente în timpul examinării IRM a pacienților cu un implant Aesculap cunoscut. Însă nu poate fi făcută o afirmație universal valabilă cu privire la interacțiunea implanturilor Aesculap cu un anumit aparat IRM ținând seama de mediul individual aplicat.

În principiu, se recomandă reducerea posibilelor riscuri prin folosirea unei forțe reduse a câmpului cu un indice redus de HF (câmp înalt) — energie și o lungime mai mare a undei. În procesul de imagistică, trebuie să se prefere secvențele cu o rată de absorbție specifică scăzută (SAR).

Vă rugăm să ne contactați dacă aveți întrebări.

Aesculap AG

Semnătură indescifrabilă

Dr. Thomas Weik
Director General Cercetare și Dezvoltare
Asistență materială-științifică și de reglementare pentru pre-dezvoltare

Semnătură indescifrabilă

Dr. Ina Wustefeld
Director pentru Afaceri Medico-Științifice

Referințe

1. Manual de referință pentru siguranța rezonanței magnetice, implanturi și dispozitive *(Reference Manual for Magnetic Resonance Safety, Implants, and Devices):* 2010 Edition, F G. Shellock, Biomedical Research Publishing Group Los Angeles, CA

2. Proceduri RM și implanturi, materiale și dispozitive biomedicale: actualizare în 1993 *(MR Procedures and Biomedical ImplanIs, Materials, and Devices)*: 1993 Update, F.G Sfiellock, S. Morisoli, E. Kanal, Radiology, 1993, 189, pp. 587-599

3. Implanturi și dispozitive medicale: evaluarea interacțiunilor câmpului magnetic cu un sistem RM cu 3,0 Tesla *(Biomedical Implants and Devices: Assessment of Magnetic field Interactions with a 3.0 Tesla MR system),* F. G. Shellock, Journal of Magnetic Resonance Imaging 2002, 16:721-732

4. Imagistica RM cu câmp magnetic puternic și implanturi biomedicale metalice: o evaluare in vitro a forțelor de deflecție și a schimbărilor de temperatură induse la protezele mari *(High Field Strength MR Imaging and metallic Biomedical Implants: an in Vitro Evaluation of Deflection Forces and Temperature Changes Induced in Large Prostheses),* F.G. Shellock, J. Crues, Radiology 1987, 165 (P): 150

5. Informații privind siguranța MR cu Tesla de 3,0 pentru implanturi și dispozitive *(3.0-Tesla MR Safety Information for Implants and Devices),* material disponibil la adresa http www.mrisafe ty.com, la secțiunea Informații privind siguranța (Safety Information).

6. Teste privind căldura în condiții RM pe implanturi sensibile la RM *(MR Heating Tests of MR Critical Implants)*, Guest Editorial
   W. Kainz, Journal of Magnetic Resonance Imaging, 26:450-451, 2007

Traducere din engleză în română a unei copii electronice a unui act autentic

……

MINISTRY OF JUSTICE

I the undersigned, **POP MARIANA**, as an interpreter and translator authorised for ENGLISH under Authorisation No 6426 of 17 October 2002, issued by the Ministry of Justice in Romania, hereby certify the accuracy of the translation from English into Romanian, that the text submitted was translated in full, with no omissions and that, by the translation, the content and meaning of the document was not distorted. Translator,

POP MARIANA
Traducător autorizat
Autorizaţia nr 6426

……

MINISTERUL JUSTITIEI

Subsemnata **POP MARIANA**, interpret şi traducător autorizat pentru limba ENGLEZĂ, în temeiul autorizaţiei nr. 6426 în data de 17 octombrie 2002, eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba engleză în limba română, că textul prezentat a fost tradus complet, fără omisiuni şi că, prin traducere, înscrisului nu i-a fost denaturat conţinutul şi sensul.

Traducător

POP MARIANA
Traducător autorizat
Autorizaţia nr 6426