

BVI

Beaver® Cataract Knives

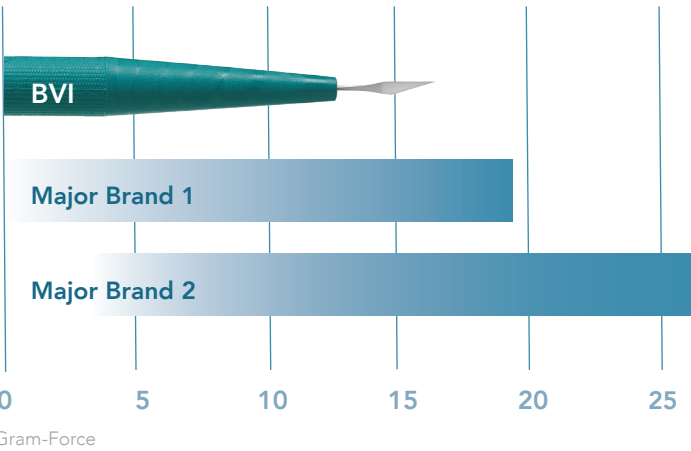
Trusted Performance, Precision and Innovation

Beaver-Visitec International, Inc. (BVI) offers a wide range of conventional knives for cataract surgery. Beaver® Slit, Sideport, Crescent and Micro-Sharp® knives come in a wide range of sizes to meet the needs of ophthalmic surgeons.



Unprecedented Sharpness and a 15-50% Less Insertion Force that Beats the Competition*

Knife Insertion Force Into Porcine Cornea

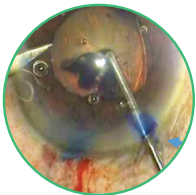


Beaver Knives Are Specialized For the Specific Task at Hand

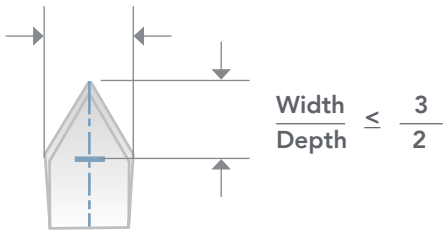
Brand	Slit/Phaco	Sideports	IOL Insertion
Xstar	✓		
MVR		✓	
Optimum		✓	
Micro-Sharp		✓	
Xstar-Crescent			✓

Please check table to match with the brand.

BVI TIP: Did you know you can drip Trypan Blue on the blade to help mark incision location?




BVI TIP: Did you know Beaver knives have a depth indicator? The depth indicator represents the tunnel length.

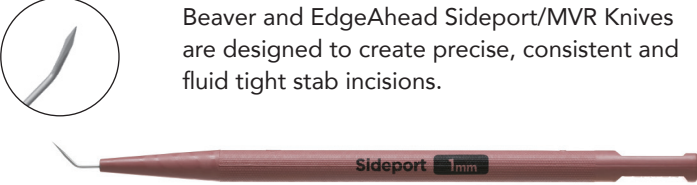


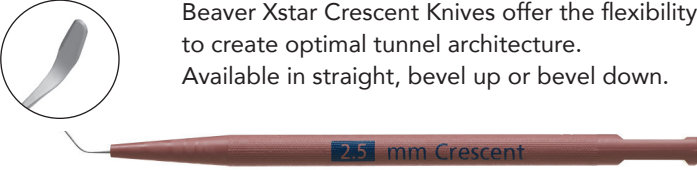
Knife sizes	Reference line from tip
1.8 mm and 2.0 mm	1.75 mm
> 2.0 mm	2 mm

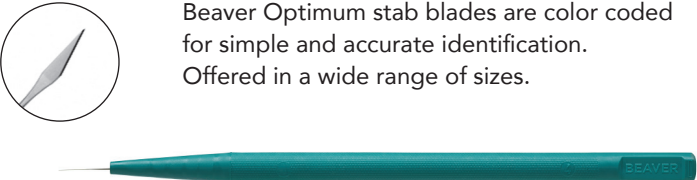


*Comparison testing performed on leading manufacturers’ ophthalmologic slit knife, results available on file at BVI, average values shown.

Beaver® Xstar Slit Knives		Description	Single Bevel	Double Bevel
 <p>Beaver Xstar Slit Knives are available in a wide range of sizes designed for smooth penetration and accurate incision. 10 per box.</p>		1.8 mm; angled 45 degrees	373718	–
		2.2 mm; angled 45 degrees	373722	370822
		2.4 mm; angled 45 degrees	373724	370824
		2.5 mm; angled 45 degrees	373725	370825
		2.6 mm; angled 45 degrees	373726	–
		2.65 mm; angled 45 degrees	–	370826
		2.75 mm; angled 45 degrees	373727	370827
		2.8 mm; angled 45 degrees	373728	370828
		2.8 mm; straight	373328	–
		3.0 mm; angled 45 degrees	373730	370830
		3.0 mm; straight	373330	–
		3.2 mm; angled 45 degrees	373732	












Beaver and EdgeAhead® Sideport MVR Knives		Description	Single Bevel	Double Bevel
 <p>Beaver and EdgeAhead Sideport/MVR Knives are designed to create precise, consistent and fluid tight stab incisions.</p>		.6 mm (23G); 5 per box	585231	585232
		1.0 mm; 10 per box	–	373710
		1.1 mm width (19G); 5 per box; EdgeAhead	585240*	–
		1.15 mm (20G); 10 per box	376630*	376620

Beaver Xstar® Crescent Knives		Description	Item #
 <p>Beaver Xstar Crescent Knives offer the flexibility to create optimal tunnel architecture. Available in straight, bevel up or bevel down.</p>		2.5 mm; 55 degrees; bevel up	373807
		2.5 mm; 55 degrees; bevel down	373809
		2.5 mm; straight	373808

Beaver® Optimum™ Knives and Blades		Description	Blades 10 per box	Blades 5 per box
 <p>Beaver Optimum stab blades are color coded for simple and accurate identification. Offered in a wide range of sizes.</p>		15 degree straight (green)	374891	374881
		22.5 degree straight (slate blue)	374892	374882
		30 degree straight (black)	374893	374883
		45 degree straight (tan)	374894	–

Beaver Micro-Sharp® Blades and Beaver Micro-Unitome Knives

Beaver Micro-Sharps and Micro-Unitomes are manufactured using a propriety Electro Chemical Finishing (ECF) technology that yields consistent sharpness. Each blade/knife is color coded for easy identification.

Description		Item #
Beaver Micro-Sharp Blade 1.5 mm; 15 degrees; orange; 6 per box		377511
Beaver Micro-Unitome Knife 1.5 mm; 15 degrees; orange; 10 per box		377512
Beaver Micro-Sharp Blade 3.0 mm; 15 degrees; blue; 6 per box		377513
Beaver Micro-Unitome Knife 3.0 mm; 15 degrees; blue; 10 per box		377514
Beaver Micro-Sharp Blade 5.0 mm; 15 degrees; green; 6 per box		377515
Beaver Micro-Unitome Knife 5.0 mm; 15 degrees; green; 10 per box		377516
Beaver Micro-Sharp Blade 4.0 mm; 22.5 degrees; light blue; 6 per box		377522
Beaver Micro-Unitome Knife 4.0 mm; 22.5 degrees; light blue; 10 per box		377523
Beaver Micro-Sharp Blade 3.5 mm; 30 degrees; black; 6 per box		377530
Beaver® Micro-Unitome Knife 3.5 mm; 30 degrees; black; 10 per box		377531
Beaver® Micro-Unitome Knife 3.0 mm; 45 degrees; tan; 10 per box		377546

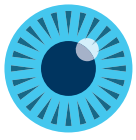
Beaver-Visitec International, Inc.

500 Totten Pond Road – 10 CityPoint, Waltham, MA 02451
Tel: 1.866.906.8080 Fax: 1.866.906.4304
bvimedical.com, endooptiks.com

Beaver-Visitec International Sales Ltd

85b Park Drive, Milton Park,
Abingdon, Oxfordshire, OX14 4RY, UK
Tel: 44.1865.601.256 Fax: 44.1865.595.761





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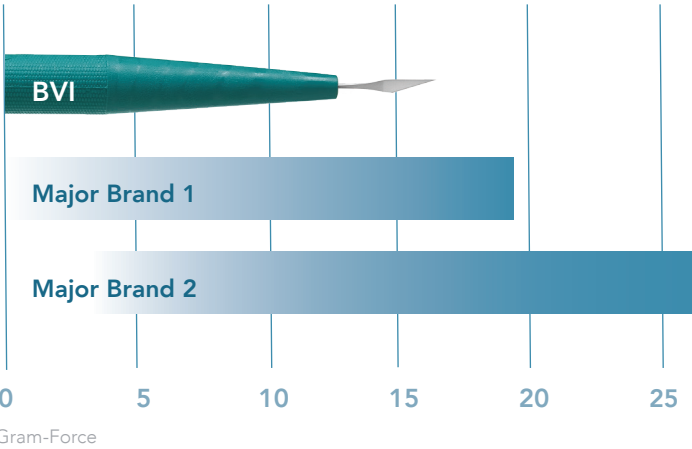


Beaver®
Knives and Blades

bvimedical.com

Unprecedented Sharpness and a 15-50% Less Insertion Force That Beats the Competition*

Knife Insertion Force Into Porcine Cornea

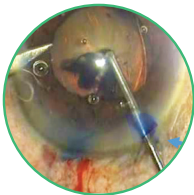


Beaver Knives Are Specialized For the Specific Task at Hand

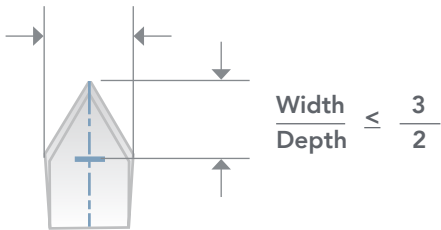
Brand	Slit/Phaco	Sideports	IOL Insertion
Xstar	✓		
MVR		✓	
Optimum		✓	
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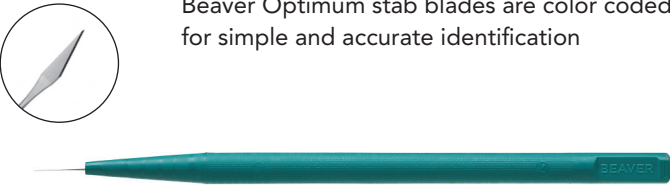
**Jhanji, V.; Chan E.; Das S.; Zhang H.; Vajpayee, RB. Trypan blue dye for anterior segment surgeries. Eye (2011) 25, 1113-1120



Beaver Xstar Slit Knives		Description	Single Bevel	Double Bevel
 <p>Beaver Xstar Slit Knives are available in a wide range of sizes designed for smooth penetration and accurate incision, 10/Bx</p>		1.8 mm, Angled 45 degrees	373718	–
		2.2 mm, Angled 45 degrees	373722	370822
		2.4 mm, Angled 45 degrees	373724	370824
		2.5 mm, Angled 45 degrees	373725	370825
		2.6 mm, Angled 45 degrees	373726	–
		2.65 mm, Angled 45 degrees	–	370826
		2.75 mm, Angled 45 degrees	373727	370827
		2.8 mm, Angled 45 degrees	373728	370828
		2.8 mm, Straight	373328	–
		3 mm, Angled 45 degrees	373730	370830
		3 mm, Straight	373330	–
		3.2 mm, Angled 45 degrees	373732	












Beaver and EdgeAhead Sideport MVR Knives		Description	Straight	Angled
 <p>Beaver and EdgeAhead Sideport/MVR Knives are designed to create precise, consistent and fluid tight stab incisions</p>		23G, .6 mm, 5/Bx	585231	585232
		20G, 1.15 mm, 10/Bx	376630	376620
		19G, 1.1 mm, EdgeAhead, 5/Bx	585240	–
		1.2 mm, Sideport, 10/Bx	–	373712
		1 mm, 10/Bx	–	373710
		2 mm, Double bevel, 10/Bx	–	370820

Beaver Xstar Crescent Knives		Description	SKU #
 <p>Beaver Xstar Crescent Knives offer the flexibility to create optimal tunnel architecture, 10/Bx</p>		2.5 mm, 55 Degrees, Bevel up	373807
		2.5 mm, 55 Degrees, Bevel down	373809
		2.5 mm, Straight, Bevel up	373808

Beaver Optimum Knives and Blades		Description	Knives 10/Bx	Blades 5/Bx
 <p>Beaver Optimum stab blades are color coded for simple and accurate identification</p>		15 Degrees, Straight, Green	374891	374881
		22.5 Degrees, Straight, Slate blue	374892	374882
		30 Degrees, Straight, Black	374893	374883
		45 Degrees, Straight, Tan	374894	–

Beaver Micro-Sharp Blades and Beaver Micro-Unitome Knives

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Description		SKU #
Beaver Micro-Sharp Blade 1.5 mm, 15 Degrees, Orange, 6/Bx		377511
Beaver Micro-Unitome Knife 1.5 mm, 15 Degrees, Orange, 10/Bx		377512
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Beaver Micro-Unitome Knife 3 mm, 15 Degrees, Blue, 10/Bx		377514
Beaver Micro-Sharp Blade 5 mm, 15 Degrees, Green, 6/Bx		377515
Beaver Micro-Unitome Knife 5 mm, 15 Degrees, Green, 10/Bx		377516
Beaver Micro-Sharp Blade 4 mm, 22.5 Degrees, Light blue, 6/Bx		377522
Beaver Micro-Unitome Knife 4 mm, 22.5 Degrees, Light blue, 10/Bx		377523
Beaver Micro-Sharp Blade 3.5 mm, 30 Degrees, Black, 6/Bx		377530
Beaver Micro-Unitome Knife 3.5 mm, 30 Degrees, Black, 10/Bx		377531
Beaver Micro-Unitome Knife 3 mm, 45 Degrees, Tan, 10/Bx		377546

FOR COMPLETE PRODUCT INSTRUCTIONS, PLEASE REFER TO THE BVI IFU OR PRODUCT INSERT

Certificate Number US19/81841492

The management system of

Beaver-Visitec International, Inc.

500 Totten Pond Rd - 10 CityPoint,
Waltham, MA, 02451, United States

Dun & Bradstreet D-U-N-S identification number : 00-140-6024

has been audited against the criteria stated below and found to conform to those criteria for the scope
contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) –
Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D / 21 CFR 821

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-04-02 until Expiry Date: 2022-04-02
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-05-18

Issue 1. Certified since 2019-04-02

Authorised by J Hall
Business Manager



Jonathan M. Hall

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Page 1 of 2



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extent of the law

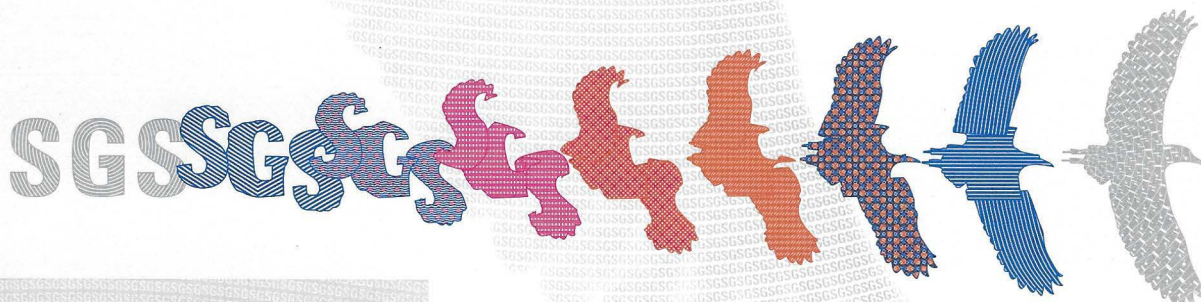
Beaver-Visitec International, Inc.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design, development and manufacture of sterile ophthalmic needles and cannulae, sterile ophthalmic surgical instruments, sterile fluid distribution sets, sterile viscoelastic solutions and sterile procedure kits. Manufacture of sterile semi-permeable adhesive wound dressings and drapes for use in ophthalmic surgery. Design, development and manufacture of sterile surgical blades, knives and trephines, sterile cystotomes, sterile dissectors, sterile probes, sterile retractors, sterile rotators, sterile dilators, sterile spatulas, sterile specula, sterile filters, sterile and non-sterile eye shields, sterile corneal light shields, sterile ENT, sterile surgical spears, sponges, absorbent swabs and sticks, sterile ocular markers and surgical glides, electrosurgical coagulation systems including sterile and non-sterile cables, non-sterile bipolar forceps and sterile erasers, sterile fluid collection bags with or without wicks, sterile instrument wipes, sterile and non-sterile electro-cautery devices, ophthalmic powered hand-pieces including sterile and non-sterile burrs, sterile ophthalmic intubation sets, sterile absorbable and sterile and non-sterile non-absorbable punctal occluders, I-Rings and sterile procedure kits for use in ophthalmic surgery.




DECLARATION OF CONFORMITY

Legal Manufacturer:	Beaver-Visitec International, Inc. 500 Totten Pond Road – 10 CityPoint Waltham, MA 02451 United States
Authorised Representative:	Vitrex B.V. Seggelant-Noord 2 3237 MG Vierpolders. The Netherlands
Products:	Specialty Blades, Knives and single use accessories (Product Code Listing attached)
Classification:	Specialty Blades and Knives, including Swivel Fixation Ring 372242, Class IIa. Rule 6; Teflon Block 9729 is Class I, Rule 1
Conformity Assessment Route:	Specialty Blades and Knives, Annex II (Full Quality Assurance) and Annex VII (Class I, Self-Declaration)

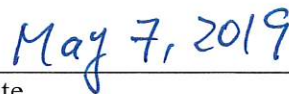
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and Council Directive 2007/47/EC of 5 September 2007. All supporting documentation is retained under the premises of the manufacturer, who is exclusively responsible for this Declaration of Conformity.

List of Harmonized/Other Standards:	EN ISO 13485:2016, EN 556-1:2001, BS EN ISO 14644-1:2015, EN ISO 15223-1:2016, ISO 8601:2016, EN ISO 14971:2012, EN ISO 10993-1:2009, EN ISO 14155-1:2011, EN 1041:2008, EN ISO 11137-1:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11135:2007
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany
Notified Body Number:	0123
EC Certificate number:	G1 103871
Start of CE marking:	N/A

Signed: _____


Regina Shih
Global Vice President Quality and Regulatory
Waltham, MA

Date _____



Products covered under Declaration of Conformity for Specialty Blades, and Knives:

Cat. No.	Description
BEAVER6400	Beaver® Mini-Blade
BEAVER6600	Beaver® Lamellar Blade, 60°, bevel up
BEAVER6610	Beaver® Lamellar Blade, sharp all around
BEAVER6700	Beaver® Mini-Blade
BEAVER6900	Beaver® Mini-Blade
BEAVER6910	Beaver® Cleft Palate Blade 60°
364820	Beaver® Mini-Blade , Bulk Sterile
364822	Beaver® Mini-Blade , Bulk Sterile
364823	Beaver® Mini-Blade , Bulk Sterile
370145	Beaver® Xstar Safety Slit Knife 2.5 mm 45° Bevel Up
370146	Beaver® Xstar Safety Slit Knife 2.6 mm 45° Bevel Up
370157	Atomic Edge® Safety Slit Knife 3.0mm
370159	Atomic Edge® Safety Slit Knife 2.8mm
370225	Atomic Edge® Safety Accurate Depth Knife 250 micron
370230	Atomic Edge® Safety Accurate Depth Knife 300 micron
370235	Atomic Edge® Safety Accurate Depth Knife 350 micron
370240	Atomic Edge® Safety Accurate Depth Knife 400 micron
370250	Atomic Edge® Safety Accurate Depth Knife 500 micron
370255	Atomic Edge® Safety Accurate Depth Knife 550 micron
370260	Atomic Edge® Safety Accurate Depth Knife 600 micron
370262	Atomic Edge® Safety Accurate Depth Knife 625 micron
370265	Atomic Edge® Safety Accurate Depth Knife 650 micron
370410	Beaver® Neuro-Sharp Blade Boyonet Sickle
370420	Beaver® Neuro-Sharp Blade, Bayonet Arachnoid
370822	Beaver® Xstar Slit Knife 2.2mm 45° Double Bevel
370824	Beaver® Xstar Slit Knife 2.4mm 45° Double Bevel
370825	Beaver® Xstar Slit Knife 2.5mm 45° Double Bevel
370826	Beaver® Xstar Slit Knife 2.65mm 45° Double Bevel
370827	Beaver® Xstar Slit Knife 2.75mm 45° Double Bevel
370828	Beaver® Xstar Slit Knife 2.8mm 45° Double Bevel
370830	Beaver® Xstar Slit Knife 3.0mm 45° Double Bevel
371400	Beaver® Bent Blade, 45 degrees, sharp all around
372242	Beaver® Swivel Fixation Ring
373025	Beaver® Xstar Kojo Safety Slit 2.5 mm 45° Bevel Up
373032	Beaver® Xstar Kojo Safety Slit 3.2 mm 45° Bevel Up
373328	Beaver® Xstar Slit Knife, 2.8mm, straight
373330	Beaver® Xstar Slit Knife, 3.0mm, straight
373332	Beaver® Xstar Slit Knife, 3.2mm, straight
373432	Beaver® Xstar Implant Knife, 3.2mm, 45° Bevel Up
373710	Beaver® Sideport Knife, 1 mm 45°
373712	Beaver® Sideport Knife, 1.2mm 45°
373718	Beaver® Xstar Slit Knife 1.8mm 45° Bevel Up
373722	Beaver® Xstar Slit Knife 2.2mm 45° Bevel Up
373724	Beaver® Xstar Slit Knife 2.4mm 45° Bevel Up

373725	Beaver® Xstar Slit Knife 2.5mm 45° Bevel Up
373726	Beaver® Xstar Slit Knife 2.6mm 45° Bevel Up
373727	Beaver® Xstar Slit Knife 2.75mm 45° Bevel Up
373728	Beaver® Xstar Slit Knife 2.8mm 45° Bevel Up
373730	Beaver® Xstar Slit Knife 3.0mm 45° Bevel Up
373732	Beaver® Xstar Slit Knife 3.2mm 45° Bevel Up
373741	Beaver® Xstar Implant Knife 4.1mm 45° Bevel Up
373752	Beaver® Xstar Implant Knife, 5.2mm, 45 ° Bevel Up
373807	Beaver® Xstar Crescent Knife, 2.5mm, 55° Bevel Up
373808	Beaver® Xstar Crescent Knife, 2.5mm, 55° Straight
373809	Beaver® Xstar Crescent Knife, 2.5mm, 55° Bevel Down
374410	Beaver® Debakey Blade 5mm
374562	Beaver® Mini-Blade
374580	Beaver® Arthro-Lok Hoe 60° 4mm Blade
374710	Beaver® Debakey Blade 8mm
374755	Beaver® Pocket™ Scleral Knife 2.25mm 60°
374769	Beaver® Mini-Blade® Surgical Blade 180°
374810	Beaver® Debakey Blade 10mm
374821	Beaver® Mini Blade® Contains 100 Blades 376500
374881	Beaver® Optimum™ Blade 15° Straight
374882	Beaver® Optimum™ Blade 22.5° Straight
374883	Beaver® Optimum™ Blade 30° Straight
374884	Beaver® Optimum™ Blade 45° Straight
374890	Beaver® Optimum™ Sideport Knife 15° Bent Left 30°
374891	Beaver® Optimum™ Knife straight, 15°
374892	Beaver® Optimum™ Sideport Straight Knife, 22.5°
374893	Beaver® Optimum™ Sideport Straight Knife, 30°
374894	Beaver® Optimum™ Sideport Straight Knife, 45°
374900	Beaver® Mammoplasty Blade, 270°
375100	Beaver® Cataract Blade 19.0mm L x 1.4mm W
375210	Beaver® Cataract Blade, 20.5mm L x 1.7mm W
375220	Beaver® Cataract Blade, 25.5mm L x 2.2mm W
375435	Beaver® Beaverguard™ Guarded .35mm Depth Blade
375450	Beaver® Beaverguard™ Guarded .50mm Depth Blade
375505	Beaver® Slit Blade 1.5mm, Straight
375700	Beaver® Sclerotome™ Blade, Multi Sided
375701	Beaver® Sclerotome™ Blade, sharp all around
375910	Beaver® Needle Blade 3.0mm Cutting Edge
375920	Beaver® Needle Blade 5.0mm Cutting Edge
375930	Beaver® Needle Blade, 7.0mm Cutting Edge
375940	Beaver® Needle Blade 1.5mm Cutting Edge
376083	Beaver® Arthro-Lok® Retrograde 4mm Blade
376086	Beaver® Arthro-Lok® Pointed Retrograde 4mm Blade
376100	Beaver® Mini-Blade®
376300	Beaver® Mini-Blade®
376401	Beaver® Mini MIS 6400

376480	Beaver® Arthro-Lok®, Round Tip 4mm Blade
376481	Beaver® Arthro-Lok®, Round Tip 4mm Blade (Flat)
376482	Beaver® Arthro-Lok®, Round Tip 4mm Blade
376500	Beaver® Mini-Blade®
376620	Beaver® Sideport Knife 1.15mm 45°
376780	Beaver® Arthro-Lok®, Pointed Tip Curve L, 4mm Blade
376800	Beaver® Tonsillectomy Blade
376980	Beaver® Arthro-Lok®, Mini-banana 4mm Blade
376981	Beaver® Mini-Banana Blade (Flat) 4mm
376984	Beaver® Arthro-Lok® Banana 4mm Blade
377081	Beaver® ArthroLok® Rosette 4mm Blade
377100	Beaver® Myringotomy Blade Downcutting Tip 45°
377110	Beaver® Myringotomy Blade Upcutting Tip, 45°
377120	Beaver® Myringotomy Blade, Offset 45°
377121	Beaver® Myringotomy Blade Narrow Shaft Offset 45°
377122	Beaver® Spear Tip Myringotomy Knife 45°
377124	Beaver® Myringotomy Knife, Lance Tip 45°
377200	Beaver® Tympanoplasty Blade, 2.5mm W, 60° Bevel Down
377210	Beaver® Tympanoplasty Blade, 2.5mm W Straight
377300	Beaver® Sickle Edge Blade 5.0mm
377511	Beaver® Micro-Sharp Blade, 1.5 mm 15°
377512	Beaver® Micro-Unitome Knife, 1.5mm 15°
377513	Beaver® Micro-Sharp Blade 3.0mm 15°
377514	Beaver® Micro-Unitome Knife 3.0mm 15°
377515	Beaver® Micro-Sharp Blade 5.0mm 15°
377516	Beaver® Micro-Unitome, Knife 5.0mm 15°
377522	Beaver® Micro-Sharp Blade 4.0mm, 22.5°
377523	Beaver® Micro-Unitome Knife 4.0mm, 22.5°
377530	Beaver® Micro-Sharp Blade 3.5mm , 30°
377531	Beaver® Micro-Unitome Knife 3.5mm 30°
377546	Beaver® Micro-Unitome Knife 3.0mm 45°
377615	Beaver® Micro-Blade 15°
378100	Beaver® Chisel Blade
378210	Beaver® Safety Sideport Knife 1.0mm 45°
378212	Beaver® Safety Sideport Knife 1.2mm 45°
378214	Beaver® Xstar Safety Slit Knife 1.4mm 45° Bevel Up
378215	Beaver® Xstar Safety Slit Knife 1.5mm 45° Bevel Up
378217	Beaver® Xstar Safety Slit Knife 1.7mm 45° Bevel Up
378218	Beaver® Xstar Safety Slit Knife 1.8mm 45° Bevel Up
378220	Beaver® Xstar Safety Slit Knife 2.0mm 45° Bevel Up
378222	Beaver® Xstar Safety Slit Knife 2.2mm 45° Bevel Up
378223	Beaver® Xstar Safety Slit Knife 2.3mm 45° Bevel Up
378224	Beaver® Xstar Safety Slit Knife 2.4mm 45° Bevel Up
378227	Beaver® Xstar Safety Slit Knife 2.7mm 45° Bevel Up
378228	Beaver® Xstar Safety Slit Knife 2.8mm 45° Bevel Up
378230	Beaver® Xstar Safety Slit Knife 3.0 mm 45° Bevel Up

378231	Beaver® Safety Sideport Knife 1.15mm 45°
378232	Beaver® Xstar® Safety Slit Knife 3.2 mm 45° Bevel Up
378234	Beaver® Xstar Safety Crescent 2.5mm 55° Bevel Up
378235	Beaver® Optimum™ Safety Sideport Knife Straight 15°
378236	Beaver® Optimum™ Safety Sideport Knife Straight 22.5
378237	Beaver® Optimum™ Safety Sideport Knife Straight 30°
378238	Beaver® Optimum™ Safety Sideport Knife Straight 45°
378300	Beaver® Chisel Blade
378400	Beaver® Chisel Blade
378800	Beaver® Chisel Blade
378822	Beaver® Xstar® Safety Slit Knife [Osher], 2.2mm 45° Double Bevel
378824	Beaver® Xstar ®Safety Slit Knife [Osher], 2.4mm 45° Double Bevel
378825	Beaver® Xstar ®Safety Slit Knife [Osher], 2.5mm 45° Double Bevel
378826	Beaver® Xstar® Safety Slit Knife, 2.65mm 45° Double Bevel
378827	Beaver® Xstar® Safety Slit Knife, 2.75mm 45° Double Bevel
378828	Beaver® Xstar® Safety Slit Knife, 2.8mm 45° Double Bevel
378829	Beaver® Xstar® Safety Slit Knife, 2.85mm 45° Double Bevel
378830	Beaver® Xstar® Safety Slit Knife, 3.0mm 45° Double Bevel
378832	Beaver® Xstar® Safety Slit Knife, 3.2mm 45° Double Bevel
379081	Beaver® Arthro-Lok® Mini-Meniscus 4mm Blade (Flat)
379082	Beaver® Arthro-Lok® Mini-Meniscus 4mm Blade
379100	Beaver® Cervical Biopsy Blade
0001520	Beaver® Micro Knife, 5.0mm, 15°
0001521	Beaver® Micro Knife, 5.0mm, 22.5°
0001522	Beaver® Micro Knife, 5.0mm, 30°
0001523	Beaver® Micro Knife, 5.0mm, 45°
0009701	Beaver® Corneal Trephine Blade 5.0mm
0009703	Beaver® Corneal Trephine Blade 5.5mm
0009705	Beaver® Corneal Trephine Blade 6.0mm
0009706	Beaver® Corneal Trephine Blade 6.25mm
0009707	Beaver® Corneal Trephine Blade 6.5mm
0009708	Beaver® Corneal Trephine Blade 6.75mm
0009709	Beaver® Corneal Trephine Blade 7.0mm
0009710	Beaver® Corneal Trephine Blade 7.85mm
0009711	Beaver® Corneal Trephine Blade 7.5mm
0009713	Beaver® Corneal Trephine Blade, 8.0mm
0009715	Beaver® Corneal Trephine Blade, 8.5mm
0009717	Beaver® Corneal Trephine Blade, 9.0mm
0009719	Beaver® Corneal Trephine Blade 7.25mm
0009721	Beaver® Corneal Trephine Blade,10.0mm
0009722	Beaver® Corneal Trephine Blade, 7.75mm
0009723	Beaver® Corneal Trephine Blade 8.75mm
0009725	Beaver® Corneal Trephine Blade 11.0mm
0009727	Beaver® Corneal Trephine Blade 8.25mm
0009728	Beaver® Corneal Trephine Blade 14.0mm
9550005	Beaver® Corneal Trephine Blade 9.5mm

9550006	Beaver® Corneal Trephine Blade 10.5mm
9550013	Beaver® Corneal Trephine Blade 11.5mm
9550025	Beaver® Corneal Trephine Blade 9.25mm
9550026	Beaver® Corneal Trephine Blade 4.0mm
9550028	Beaver® Corneal Trephine Blade 12.0mm
9550029	Beaver® Corneal Trephine Blade 13.0mm
9729	Beaver® Replacement Teflon Block Used with 1728

HISTORY SHEET

Effective Date	DESCRIPTION	INITIATOR
1/27/10	DOC separated from Technical File RTF30. The Declaration of Conformity will be it own date controlled document. Updated formatting. Added Catalog Numbers 373718, 373722, & 373724.	D. Puma
4/30/2010	Removed Catalog Numbers 375025, 375030, 375035, 375050, 375055, 375060 and correct numerical order of cat #'s, added 376700 to listing	G.Moushigian
6/25/10	Added Catalog Numbers: 370822, 370824, 370825, 370826, 370827, 370828, 370830 to listing	D. Puma
8/9/10	Removed Catalog Numbers 371600 & 374103 – Rationalized product.	D. Puma
10/04/2010	Update Manufacture, Authorized Rep and Mfg. Site Names, EC Cert Number , remove “BD” from Product/Classification/and Conformity blocks and added new Non-Safety XStar Product codes, deleted 376100 discontinued; corrected Notified Body Name and added Notified Body Number	G.Moushigian
10/20/2010	Removed 376630, part of Bidford technical file for knives, added 376100 Mini-Blade	G. Moushigian
3/16/2011	Correct EC Cert # from GB10/81383 to US10/81383	G.Moushigian
5/05/2011	Added BEAVER6400, BEAVER6600, BEAVER 6610, BEAVER6700, BEAVER6900, BEAVER6910	G.Moushigian
9/21/2011	Corrected in Classification : Specialty Blades and Knives Class IIA to Class IIa	G.Moushigian
9/28/2011	Add Catalog Number 378220 to listing	G.Moushigian
2/12/2011	Removed the following Catalog Numbers due to discontinuation: 370110, 370120, 370307, 370327, 370328, 370330, 370332, 370341, 370391, 370392, 370393, 370394, 371800, 373341, 373352, 374524, 374736, 374761, 376806, 375500, 375504, 375510, 375523, 375570, 376782, 376981, 377000, 379071, 379710	G.Moushigian
3/23/2012	Add Catalog Number 364820, 364822, 364823, 378223 to listing	G.Moushigian
7/18/2012	Add Catalog Number 376891	D. Cromwick
8/01/2012	Added Atomic Edge Trephine Blasé and Micro knives , removed Ring Cutter and Handles	G.Moushigian
8/01/2012	Added Cat #'s 373710 and 378210	G.Moushigian
12/05/2012	Added Cat #'s RD0141, RD0142, RD0221, RD0222, and RD2225	G.Moushigian

	For user assessment only	
2/19/2013	Update Signature block(Name and Title)	G.Moushigian
3/01/2013	Corrected all descriptions and removed Cat #'s RD0141, RD0142, RD0221, RD0222, and RD2225 to a separate DOC	G.Moushigian
5/24/2013	Remove Obsolete Cat#'s 373735 and 376320	G.Moushigian
11/20/2013	Added Cat # 378212	G.Moushigian
7/10/2014	Correct Description of Product Codes 370822, 370824, 370825, 370826, 370827, 370828, 370830, 378234, 370145, 370146	G.Moushigian
7/21/2014	Correct Description of Product Codes 370145, 370146	G.Moushigian
8/18/2014	Corrected title to add ... and single use accessories; Added Product Codes 372242 and 9729	G.Moushigian
10/30/2014	Correct Description of Product Code 373808 (added 55°)	G.Moushigian
12/17/2014	Correct Description of Product Codes 373432, 374881, and 374890	G.Moushigian
01/06/2015	Remove the word [Osher] from the description of 378826, 378827, 378828, 378829, 378830, 378832	G.Moushigian
01/14/2015	Remove Cat # 379400, 379500 and 379700 discontinued	G.Moushigian
11/30/2015	Change Class from II to IIa	G.Moushigian
3/25/2016	Remove Discontinue Part# 373435	G.Moushigian
11/29/16	Added new part # 373712	D. Hebert
5/11/2017	Remove Discontinue Part# 374451 and Amended EC statement	G.Moushigian
7/13/2017	Amend statement of conformity; delete Manufacturing Site and Assembly Site; add place of issue per ISO/IEC 17050-1; remove discontinued Cat#'s 376400, 376700, 376900 and 376910	G. Moushigian
5/24/2018	Legal manufacturing site address and logo updated	J. Shah
8/6/2018	Removed Discontinue Parts 375516, 377630, 378600	G.Moushigian
4/25/2019	Changed EU Rep from BVI Bidford to Vitreq; updated standards, notified body to TUV, EC certificate number, and manufacturer's statement. Removed discontinued parts: 373835, 374520, 377545, 374723, 374751, 374752, 374756, 374805, 374822, 374823, 375520, 375521, 375522, 376600, 376610, 374820.	J. Shah