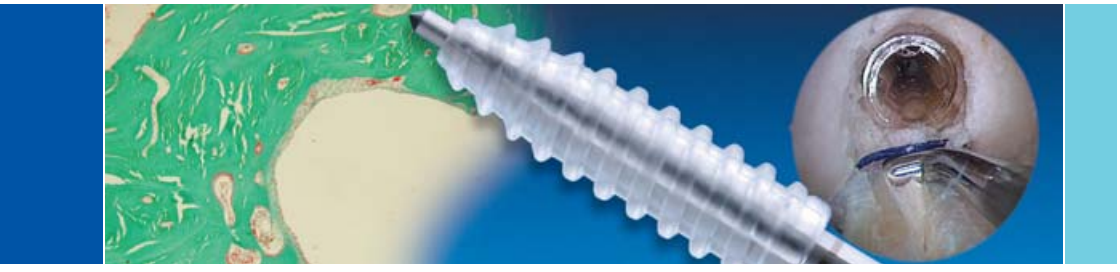
ENDOWORLD
OSM19-5-E/06-2007

MegaFix® –

The Bioabsorbable Interference Screw



KARL STORZ – SPORTS MEDICINE, Inc.

STORZ
KARL STORZ — ENDOSKOPE
THE DIAMOND STANDARD

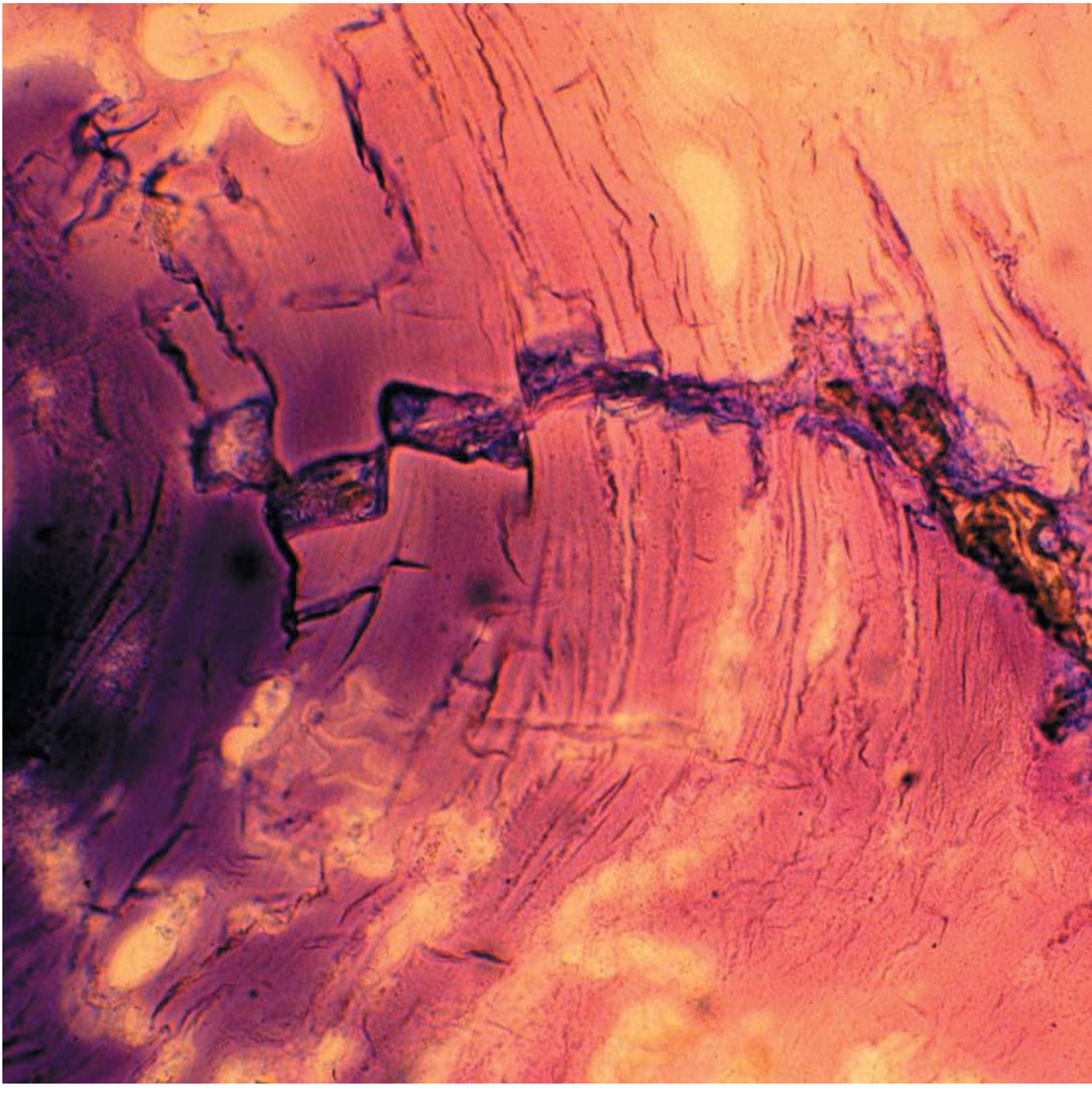
MegaFix® –

The Bioabsorbable Interference Screw

Provides the ideal synthesis of

- mechanical strength
- biocompatibility
- biodegradation
- osseous replacement.

The MegaFix® screw has been designed to meet the challenges associated with current bioabsorable interference screws. The unique CrossDrive™ hex-to-tip screwdriver interface, combined with superior material strength, maximizes torsional strength, allowing for Bone-Tendon-Bone fixation without pre-tapping.



The MegaFix® patented thread design starts easily, while minimizing tissue damage.

The biodegradable composition – A critical factor

Biodegradability provides the obvious advantages such as

- anatomic joint line fixation of soft tissue grafts
- undistorted radiological imaging
- uncompromised revision surgery
- minimized risk of tissue laceration

These advantages have led to the increase in the use of biodegradable interference screws for the treatment of cruciate tears.

However many of the screws currently available vary in their degree of biodegradability due to their chemical composition. Many consist of a high molecular weight poly-(L-lactide), also know as PLLA. During revision procedures, implants made of this material have been removed intact, several years following the original procedure (1-3). If biodegradation is an outcome required of an interference screw, then one must consider the material composition when selecting the implant.

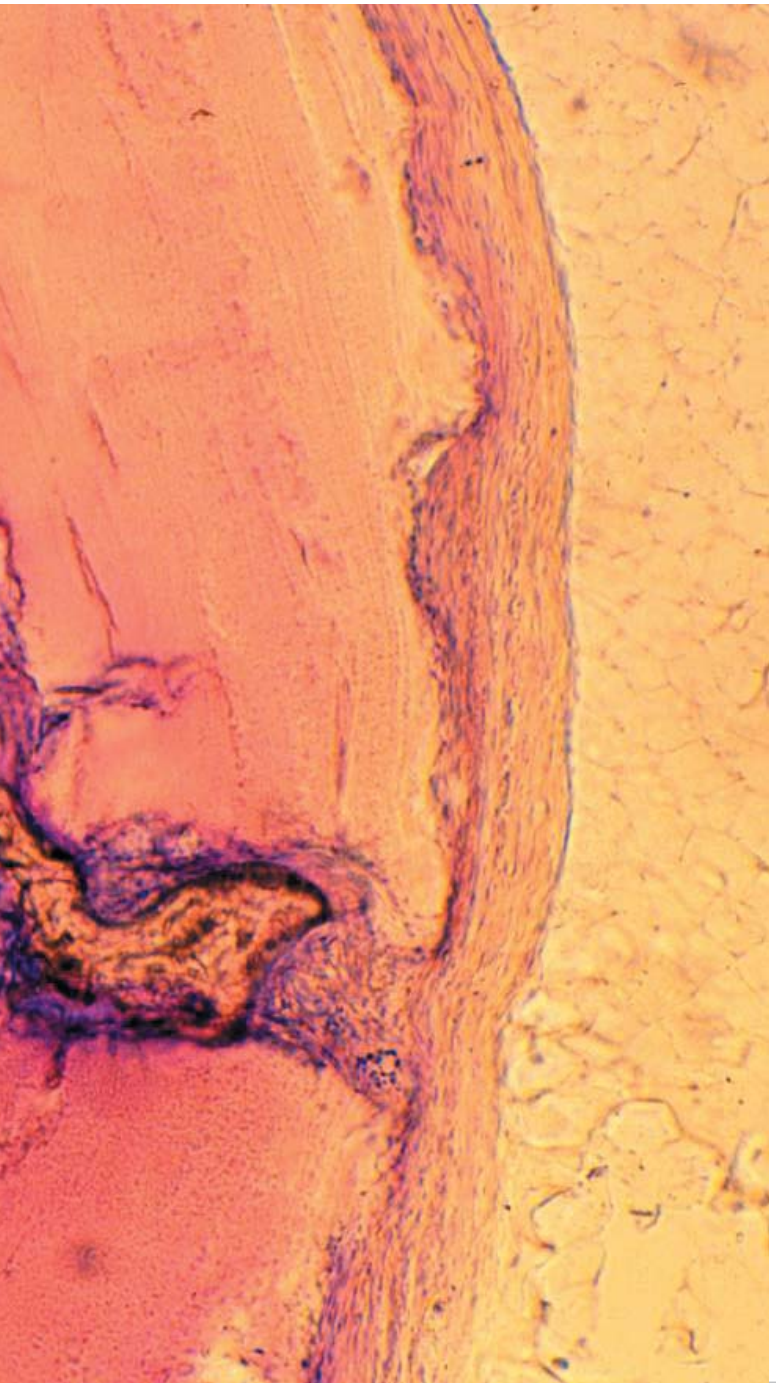


Fig. 1
Poly-(L-co-D,L-lactide) implant 15 months after implantation in an animal model. While the implant breaks down into fragments, there is already an ingrowth of newly formed bone trabeculae (with permission of W.B Saunders, Arthroscopy 16: 305-321, 2000).

The material

The MegaFix® device is the only biodegradable interference screw made of a unique amorphous stereocopolymer, poly-(L-co-D, L-lactide) 70:30. This material and consequently the MegaFix® screw, degrades protractedly over time without an adverse inflammatory tissue response. Thus the MegaFix screw provides optimal biocompatibility characterized by a thin, non-reactive, tissue-implant interface (3).

Degradation

The complete degradation of high molecular weight and crystalline PLLA screws has not been established. In contrast, the MegaFix® material (amorphous stereo copolymer) has demonstrated complete tissue clearance 18 months following implantation in an animal model, with a 2.5 year follow-up (3).

Osseous replacement

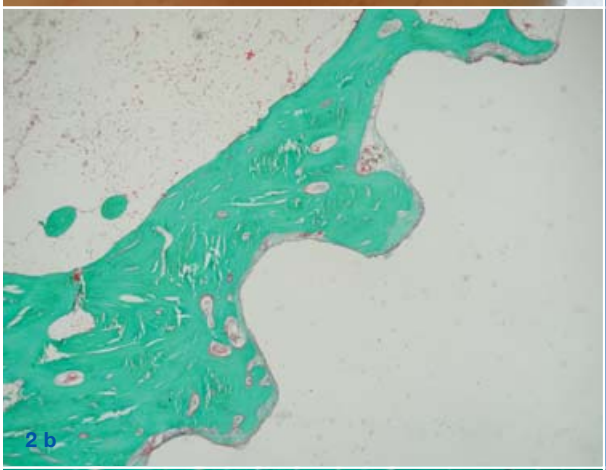
It has been demonstrated that due to the amorphous stereocopolymer structure and its protracted degradation, there is a continuous ingrowth of newly formed bone starting around 18 months (3).

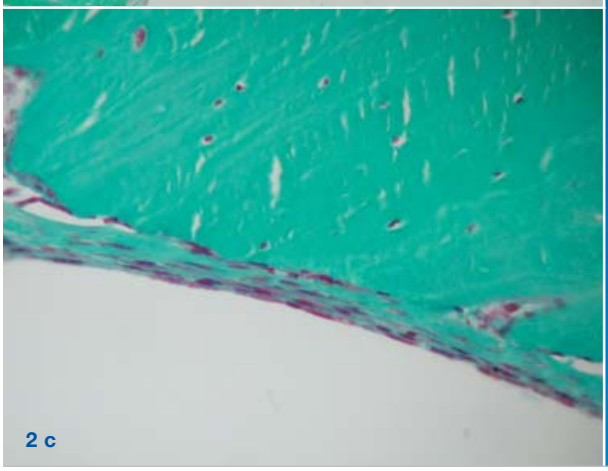
Biocompatibility

Follow up studies have shown excellent biocompatibility following implantation of the MegaFix® screw. No adverse inflammatory response has developed (Fig. 2).

Fig. 2 a-c
Experimental investigation of the MegaFix® screw implanted into a proximal sheep tibia (a). There is no inflammatory tissue response and a homogeneous osseous encapsulation of the implant (b). The very thin and non-reactive tissue-implant interface indicates an excellent biocompatibility (c).


2 a


2 b


2 c


3 a

Optimized screw design

Many of today's interference screws have been designed featuring either sharp or blunt threads. Sharp threads pose a high risk of graft laceration upon full insertion, while blunt threads tend to lead to difficulties in starting the screw into the tunnel. The unique, patented design of the MegaFix® screw capitalizes upon its thread design by combining these two patterns into one (Fig. 3).

- Begin with sharp threads:

  sharp threads at the tip of the screw allow for an “easy start”, affording a reproducible and safe insertion.

- Follow with blunt threads

  blunt threads where the screw reaches its full diameter, protecting the graft from laceration while ensuring fixation strength.

Minimized risk of graft laceration

The special screw design of the MegaFix® protects the graft during insertion and, at the same time, permits reliable starting of the screw when insertion begins (Fig. 3)

Fig 3 a-b
MegaFix® Screw Design

Efficient drive-screw interface

Another problem associated with currently available bioabsorbable interference screws is their low torsional strength. If the drive screw interface is ineffective, the screw has the tendency to fail through breakage or stripping of the driver. Thus the screw cannot be fully advanced.

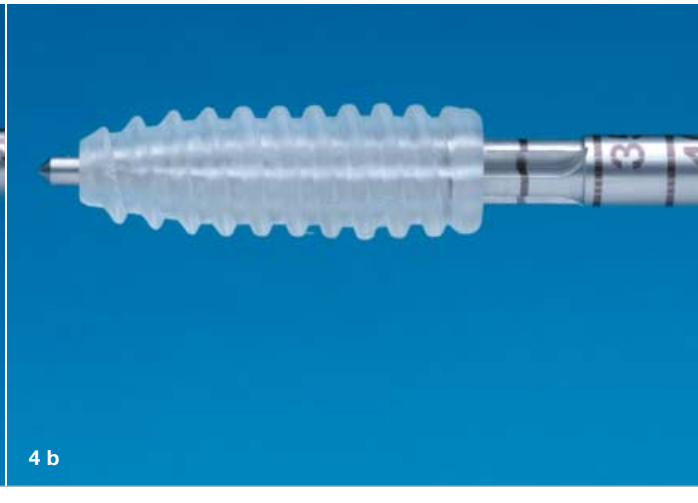
A hex-to-tip, X-like shape (CrossDrive™) has been configured into the MegaFix® screw to transfer extremely high torsional forces along its full length. This facilitates an efficient driver-screw interface, minimizing the risk of screw breakage. In addition, this optimized interface avoids slippage of the screw off the driver.

CrossDrive™ allows for an eccentric force transmission from the driver to the screw. Torsional strength measurements of various bioabsorbable interference screws have shown that many currently available screws exhibit a strength measured between 2 and 6 Nm (4). Compared to these screws, the 8 x 23 mm sized MegaFix® with CrossDrive™, demonstrated an unsurpassed mean torsional strength of 9.2 Nm (Fig. 5).

The optimized connection between the screw and the driver creates high torsional strength while avoiding slippage of the screw from the driver.

Due to excellent mechanical properties, the MegaFix® screw allows for secure bone-patellar tendon-bone as well as soft tissue graft fixation, both in anterior and posterior cruciate ligament reconstruction.

Fig. 4 a-b
MegaFix® driver with CrossDrive™.



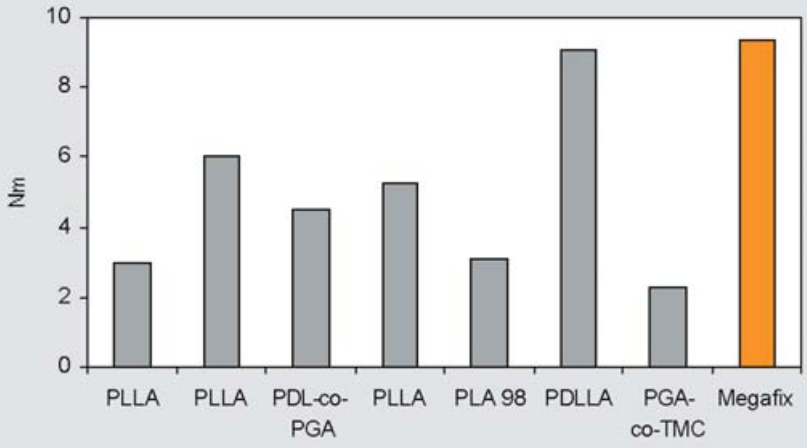


Fig. 5
Torsional strength measurements of different bioabsorbable interference screws.

Documented MegaFix® advantages

- highest torsional strength available to resist screw breakage
- optimized CrossDrive™/MegaFix® Interface to ensure complete screw insertion
- blended thread design to ease screw insertion while protecting the graft and ensuring strong fixation
- biodegradation leading to osseous replacement
- biocompatibility reducing adverse inflammatory response

Other indications:

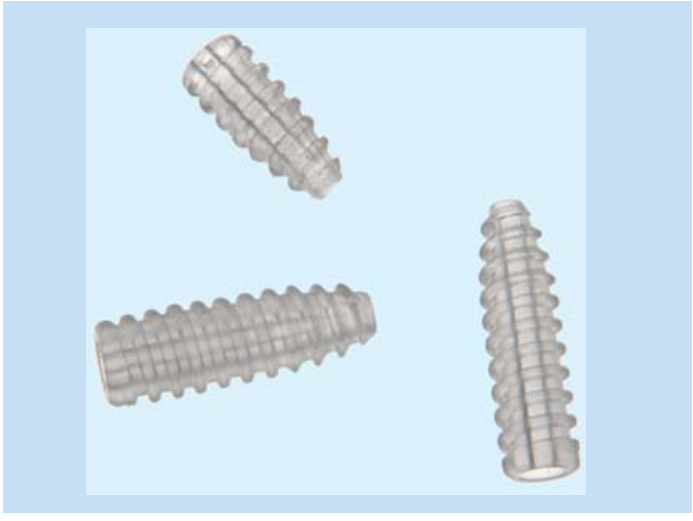
- hybrid fixation
  MegaFix® provides an ideal method of hybrid fixation. For femoral fixation, the combination with other fixation techniques (e.g. fixation button) has proved successful. For tibial fixation of a hamstring graft an additional backup (e.g. knot over a bone-onlay, tibial button – Endotack™ –, screw with washer) is recommended to prevent possible loosening of the graft.

Reference List

1. **Martinek V.; Seil R.; Lattermann C.; Watkins S.; Fu F.:**
   The fate of the poly-L-lactic acid interference screw after anterior cruciate ligament reconstruction.
   Arthroscopy 2001; 17: 73-76.
2. **Stähelin A.; Weiler A.; Rüfenacht H.; Hoffmann R.; Geissmann A.; Feinstein R.:**
   Clinical degradation and biocompatibility of different bioabsorbable interference screws: A report of six cases.
   Arthroscopy 1997; 13: 238-244.
3. **Weiler A.; Hoffmann R.; Stähelin A.; Helling H.; Südkamp NP.:**
   Current concepts: Biodegradable implants in sports medicine – The biological base.
   Arthroscopy 2000; 16: 305-321.
4. **Weiler A.; Windhagen H.; Raschke M.; Laumeyer A.; Hoffmann R.:**
   Biodegradable interference screw fixation exhibits pullout force and stiffness similar to titanium screws.
   Am J Sports Med 1998; 26: 119-128.

Notes

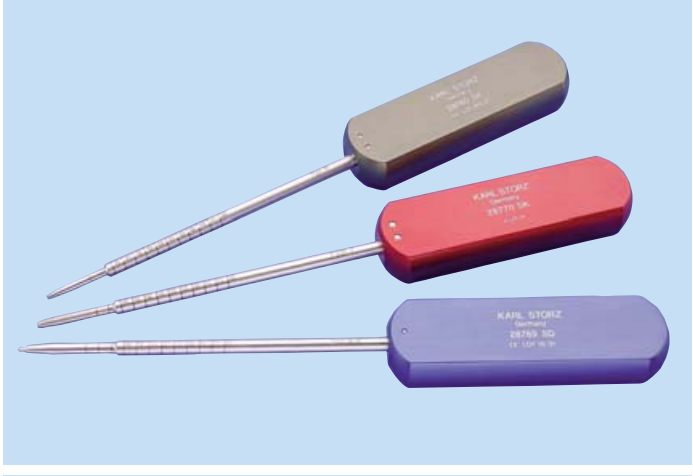
MegaFix® – The Bioabsorbable Interference Screw



The MegaFix® is available in the following sizes

Diameter	Length	Cat. No.
9 mm	23 mm	2870923 B
	28 mm	2870928 B
8 mm	19 mm	2870819 B
	23 mm	2870823 B
	28 mm	2870828 B
7 mm	19 mm	2870719 B
	23 mm	2870723 B
	28 mm	2870728 B
6 mm	19 mm	2870619 B
	23 mm	2870623 B

CrossDrive™

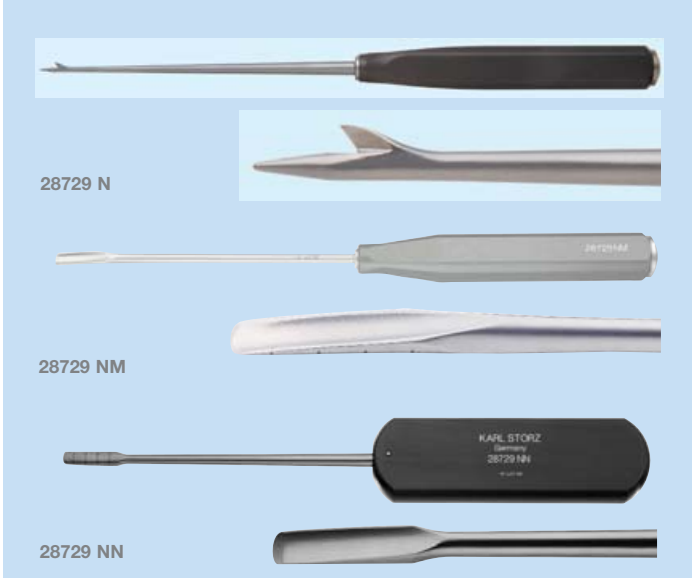


For screw insertion:

28789 SK	Screwdriver, cannulated, size 8–9
28789 SD	Screwdriver, noncannulated, size 8–9
28770 SK	Screwdriver, cannulated, size 7
28770 SD	Screwdriver, noncannulated, size 7
28760 SK	Screwdriver, cannulated, size 6
28760 SD	Screwdriver, noncannulated, size 6

Guidewire for accurate placement of the MegaFix® screw:

28789 GW	Guidewire, Nitinol, diameter 1.1 mm



Notching of the bone allows for an “easy start” of the MegaFix® screw:

28729 N	Notcher, working length 15 cm
28729 NM	Chisel for crating a bone wedge for Cruciate ligament surgery
28729 NN	Notch Chisel with broad handle, to create a bone wedge in ACL surgery

ENDOWORLD®

WWW.KARLSTORZ.COM

KARL STORZ GmbH & Co. KG
Mittelstraße 8, 78532 Tuttlingen, Germany
Postfach 230, 78503 Tuttlingen, Germany
Phone: +49 (0)7461 708-0
Fax: +49 (0)7461 708-105
E-Mail: info@karlstorz.de
www.karlstorz.com

KARL STORZ Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600, USA
Phone.: +1 / 310 / 338 8100
+1 / 800 / 421 0837
Fax: +1 / 310 / 410 5527
E-mail: info@ksea.com

KS SM

KARL STORZ – SPORTS MEDICINE, Inc.

STORZ
KARL STORZ — ENDOSKOPE
THE DIAMOND STANDARD

EW OSM-19-5-E/06-2007