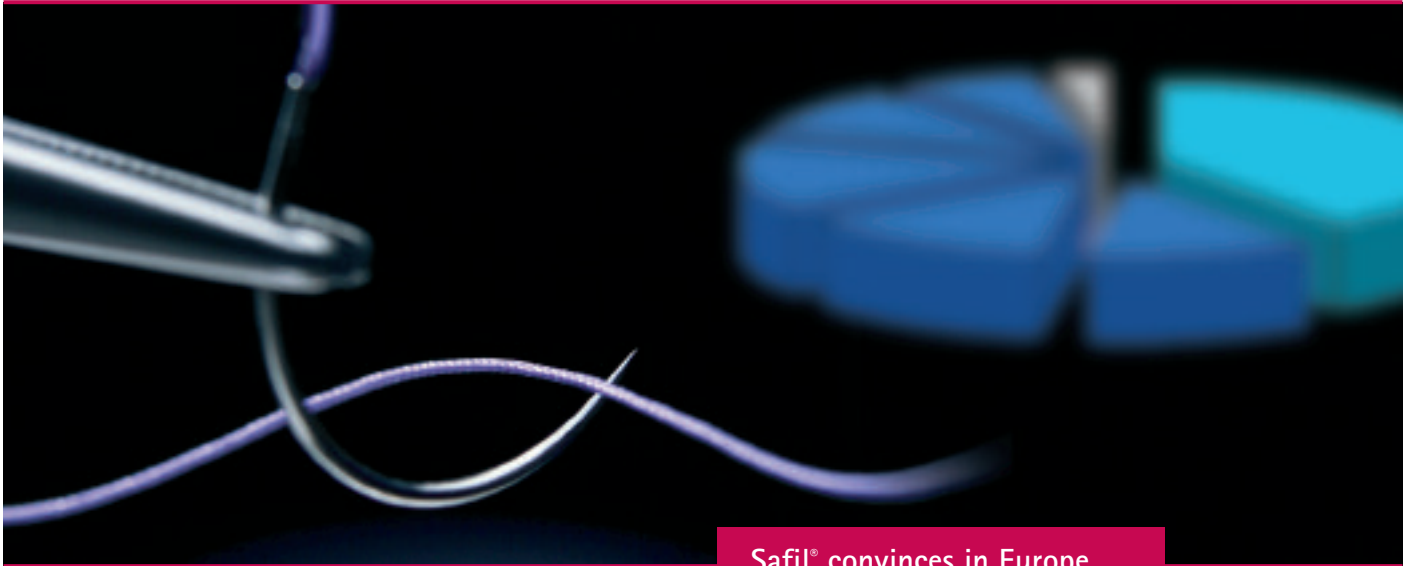


B. Braun Sutures

Safil® application tests

Scientific information



Safil® convinces in Europe

Safil®

convinces in Europe

■ Safil® application tests

In the years 2005 to 2006 a Safil® violet suture study was performed in different surgical disciplines and in different European countries.

The aim was to evaluate, underline and prove the overall positive acceptance and excellent handling performance of the suture on a broader European basis.

Austria, France, Italy, Poland, Spain and United Kingdom were included in the study (see Fig. 1).

Four different surgical disciplines were chosen (see Fig. 2):

Visceral Surgery (oesophagus, stomach, small intestine, large intestine, rectum...)

Gynaecology (uterus, ovaries, vaginal mucosa...)

Orthopaedics (knee replacement, hip, pelvic osteotomy...)

Urology (kidney, urether, urinary bladder, urethra, male genitals...)

Safil® violet was used in this test mostly in Visceral Surgery (43 %), followed by Gynaecology (28 %), Orthopaedics (16 %) and Urology (13 %) (see Fig. 2)

Having such a broad range of applications, an objective assessment of the qualities of Safil® violet was given.

The sizes of the used Safil® ranged from USP 1 down to USP 5/0. The performance of the Safil® violet were documented on standardized data sheets regularly used for application tests.

Number of Safil® tests

In total 527 suture tests with Safil® were performed in different European countries

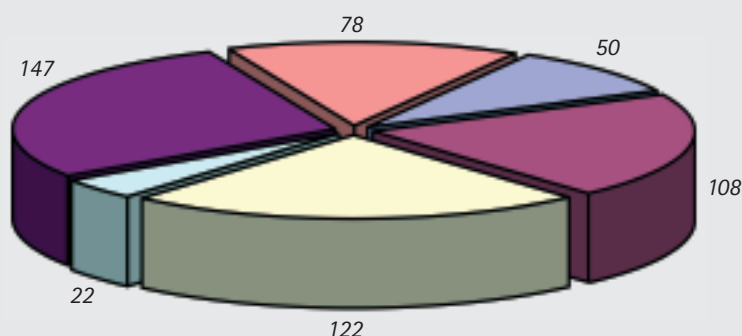


Fig. 1

Poland France Austria
Italy UK Spain

Surgical disciplines

Distribution of the overall usage of Safil® in the different surgical disciplines

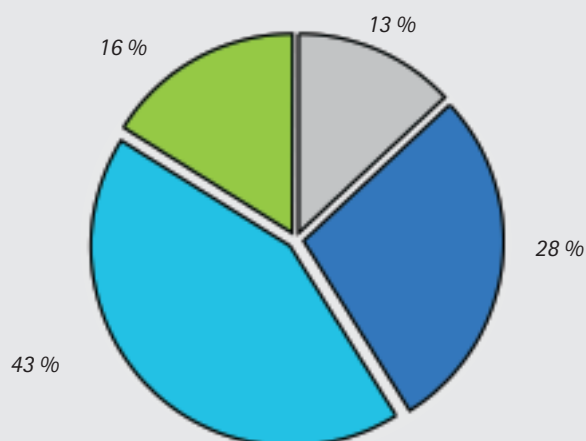


Fig. 2

Visceral Surgery Orthopaedics
Gynaecology Urology

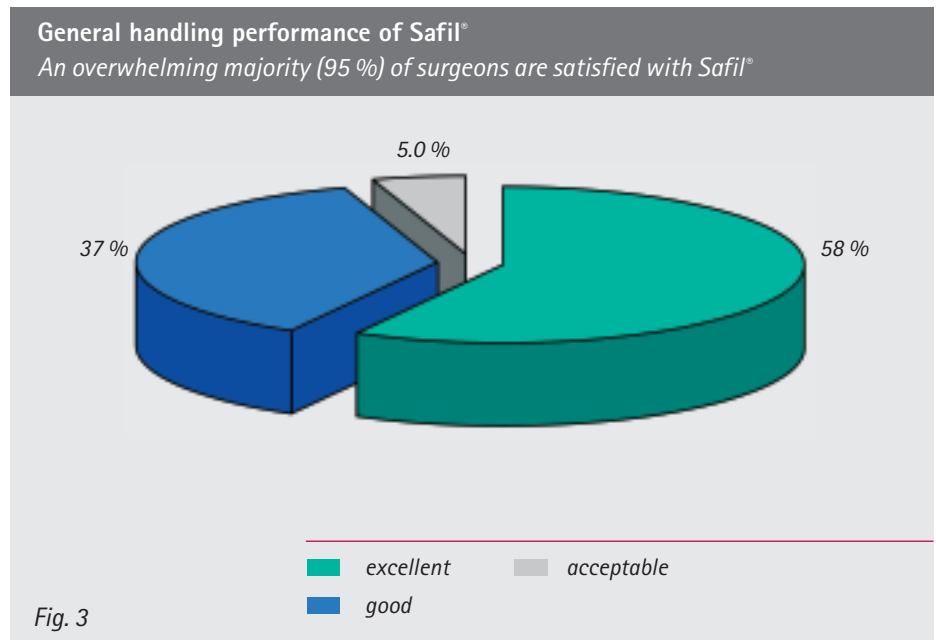


■ Results

The handling parameters asked to be ranked were the 8 most important parameters for suture tests:

- Lack of memory
- Tissue passage
- Placement of the first knot
- Knot running
- Knot safety
- Visibility of the suture
- Handling
- Knot tensile strength

The surgeons were asked to make the cross on the performance score of each handling parameter ranking the individual assessment from acceptable and good up to excellent performance. In total 527 tests were documented.



58 % of the surgeons stated the excellent handling performance of Safil® violet and 37 % stated a good performance quality. **In total, 95 % of the assessments were positive (see Fig. 3).**

In addition, more than 99 % of all interventions were finished without any suture related complaints or complications.

	1. Lack of memory	2. Tissue passage	3. Placement of first knot	4. Knot running	5. Knot safety	6. Visibility of suture	7. Handling	8. Knot tensile strength	9. General handling
excellent	57.8 %	58.2 %	58.1 %	59.8 %	56.2 %	62.5 %	58.6 %	53.2 %	58.0 %
good	38.2 %	36.2 %	34.2 %	33.5 %	35.4 %	32.6 %	35.1 %	37.5 %	37.0 %
acceptable	4.0 %	5.6 %	7.7 %	6.7 %	8.4 %	4.9 %	6.3 %	9.3 %	5.0 %

Table 1: Handling performance of Safil®

Safil[®]

convinces in Europe

Knot safety and knot tensile strength are one of the most important criteria for the definition of a good suture. Both parameter were assessed very positively (see Fig. 4).

Knot related parameters

Diagram of the most important suture parameters knot safety and knot tensile strength demonstrating very positive assessment values

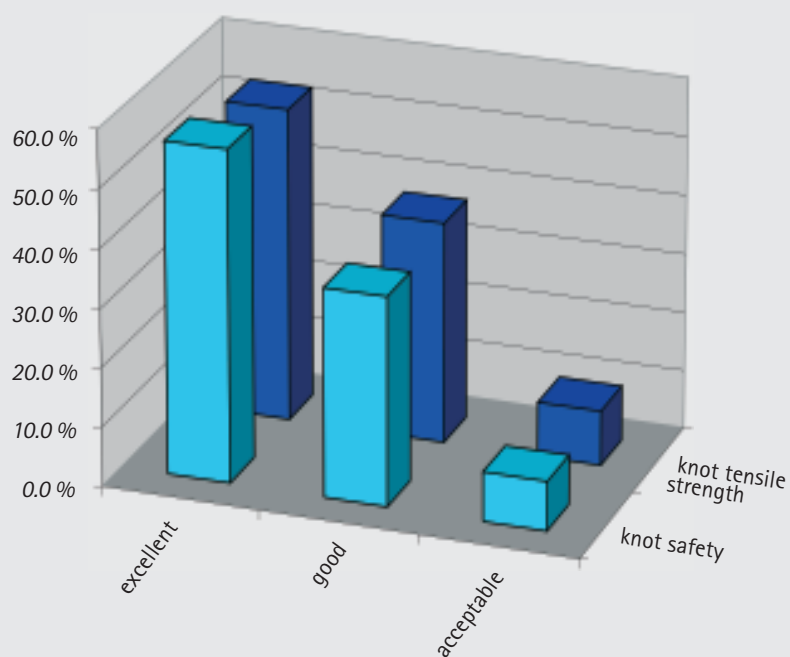
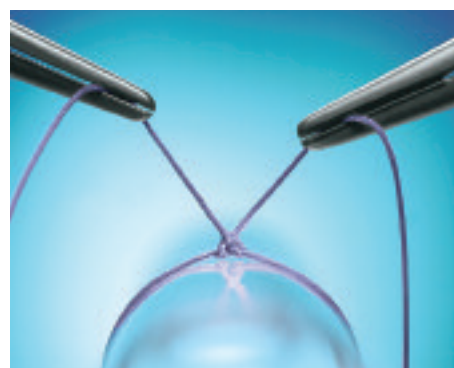


Fig. 4





Safil® convinces in Germany

■ Safil® application test Germany 2003

The application tests were performed during February and October 2003 in 150 German hospitals.

Safil® violet was used in general, vascular, thoracic and trauma surgery, as well as in gynaecology, urology and ENT in 400 cases. Safil® violet was used and benchmarked in patients 12 to 93 years old.

The surgeons informed about the performance of each parameter using a positive scale from +1 to +5, a neutral scale 0 and a negative scale from -1 to -5.

97 % of all surgeons were satisfied with Safil® violet (see Fig. 5):

- 48.1 % of all surgeons sign positive for Safil®
- 51.9 % of all surgeons confirm Safil® as good as competition

Safil® violet Evaluation Germany – Average evaluation of all suture parameters

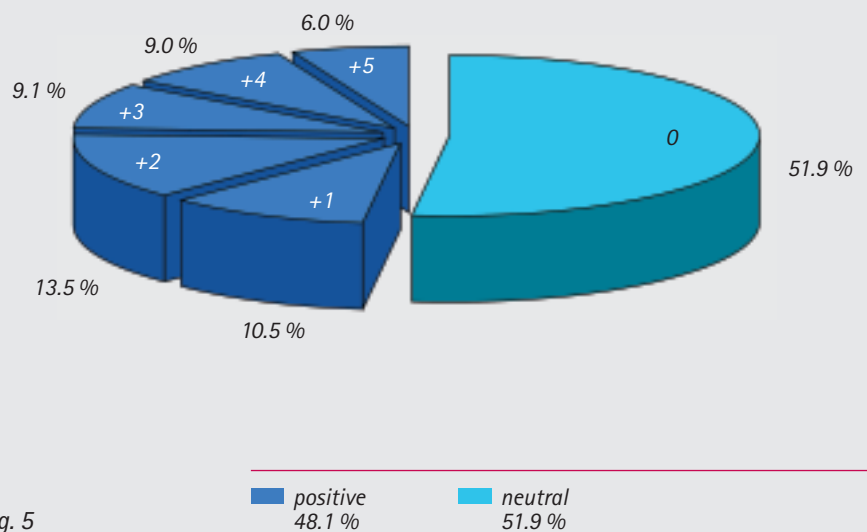


Fig. 5

	1. Lack of memory	2. Tissue passage	3. Placement of first knot	4. Knot running	5. Knot safety	6. Visibility of suture	7. Handling	8. Knot tensile strength	9. General handling	10. Average evaluation
positive	40.3 %	57.7 %	50.1 %	53.7 %	42.2 %	39.0 %	54.0 %	37.1 %	57.9 %	48.1 %
+1	10.6 %	12.6 %	12.8 %	9.9 %	7.2 %	7.2 %	12.5 %	6.0 %	15.3 %	10.5 %
+2	10.6 %	18.2 %	13.0 %	14.9 %	12.0 %	7.7 %	18.2 %	10.5 %	16.1 %	13.5 %
+3	9.1 %	12.6 %	11.8 %	9.9 %	10.0 %	8.2 %	6.4 %	4.7 %	9.0 %	9.1 %
+4	5.4 %	7.7 %	7.9 %	11.9 %	8.9 %	9.5 %	9.7 %	9.4 %	10.8 %	9.0 %
+5	4.6 %	6.6 %	4.6 %	7.1 %	4.1 %	6.4 %	7.2 %	6.5 %	6.7 %	6.0 %
neutral	59.7 %	42.3 %	49.9 %	46.3 %	57.8 %	61.0 %	46.0 %	62.9 %	42.1 %	51.9 %

Table 2: Handling performance of Safil® in Germany

Safil®

Conclusions



The assessment of nearly 1.000 documented application tests of Safil® violet in 181 European hospitals clearly demonstrate the high performance standard of this innovative absorbable suture material.

An overwhelming majority of surgeons stated Safil® as an excellent or good suture material.

This positive assessment given by the surgeons is another prove for the company B. Braun to invest in modern technology and high level research to develop products which are highly accepted by the customers.



Product information Safil®



■ Material

Polyglycolic acid
mid-term absorbable

■ Coating

Glyconate or uncoated
(USP 10/0 and 9/0)

■ Suture construction

Braided or monofil (USP 10/0 and 9/0)

■ Color

violet, undyed

■ Sizes

USP 10/0 – 2
metric 0.2 – 5

■ Tensile strength

14 days	70 %
18 days	50 %
21 days	40 %

■ Absorption

after 60 to 90 days

■ Main indications

Visceral surgery
Gynaecology
Urology
Plastic surgery
Orthopaedics
Ophthalmology



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