



Monosyn® QUICK PRODUCT REGISTRY

AN INTERNATIONAL, MULTI-CENTRIC, OPEN, PROSPECTIVE,
NON-INTERVENTIONAL STUDY TO DOCUMENT THE CLINICAL
PERFORMANCE OF Monosyn® QUICK SUTURE MATERIAL
IN DIFFERENT INDICATIONS UNDER ROUTINE CONDITIONS.

Monosyn® QUICK PRODUCT REGISTRY

AN INTERNATIONAL, MULTI-CENTRIC, OPEN, PROSPECTIVE, NON-INTERVENTIONAL STUDY TO DOCUMENT THE CLINICAL PERFORMANCE OF Monosyn® QUICK SUTURE MATERIAL IN DIFFERENT INDICATIONS UNDER ROUTINE CONDITIONS.

SYNOPSIS

DESIGN

International, multi-centric, open, prospective registry.

INDICATION

Pediatric and adult patients undergoing mucosal wound or skin closure using Monosyn Quick as suture material or women undergoing an episiotomy or pediatric patients undergoing a circumcision or phimosis or hypospadias.

SAMPLE SIZE

There is no limit in regard to the patient number per participating center.

OUTCOME PARAMETER

Details regarding safety, effectiveness and performance parameter.

FOLLOW-UP

Documentation under clinical routine conditions until day of discharge.

IN- / EXCLUSION CRITERIA

No strict inclusion – and exclusion criteria.

Patients have to give their written informed consent for the documentation of the clinical data within the registry.

DOCUMENTATION

Documentation of the data will be performed in a web based registry (www.studiesportal.com) provided by B. Braun.

Monosyn QUICK

Monosyn Quick the short-term absorption profile monofilament suture of B. Braun.



Monosyn[®] QUICK PRODUCT REGISTRY

DATA BASE


DOCUMENTATION

Clinical data will be documented in an online registry under www.studiesportal.com. Data base can be accessed by entering a personal password. After fulfilling the requirements the study management will provide the password to the investigator.

The data base contains the following categories:

- Screening (baseline / demography)
- Operation
- Day of discharge
- Optional postoperative visit performed under daily clinical routine depending on the indication and the local standard until 1 month after surgery
- Optional postoperative visit performed under daily clinical routine depending on the indication and the local standard until 3 months after surgery

Studies Portal | Deutsch | English | Français | Español |



Welcome to our online database for the documentation of your clinical results!
Dear User, Log-in access to the Internet portal has changed.
If you are logging in for the first time, the system will ask you to change your password. This is to increase the security of the portal. After you have logged in successfully, you will be able to see the databases for which you currently have access rights. You can change your password at any time, but you should change it after 6 months at the latest.

Login
User name:
Password: → Login

Change password
User name:
Old password:
New password:
New password (repeat): → Change password

Forgotten your password?
Please enter your email address in the box below and we will contact you shortly.
 → Request

impressum
Copyright 2013
Aesculap AG

ADVANTAGES / SERVICES

ADVANTAGE FOR THE CLINIC / INVESTIGATOR

- Prospective systematic collection of the hospital's own clinical data
- Use as a quality management tool
- Data can be used for posters, abstracts, and congress presentations
- Publication of the hospital's own data
- Authorship on an international, multi-centric publication depending on the recruitment performance

SERVICE OF B. BRAUN FOR THE CLINIC / INVESTIGATOR

- The usage of the online data base is free of charge
- Acquisition of the data management to ensure data quality
- Conduction of the biometric data analysis and evaluation
- Support during publication preparation

QUESTIONS / CONTACT

In the case of questions please contact the department of clinical studies within the B.Braun company.

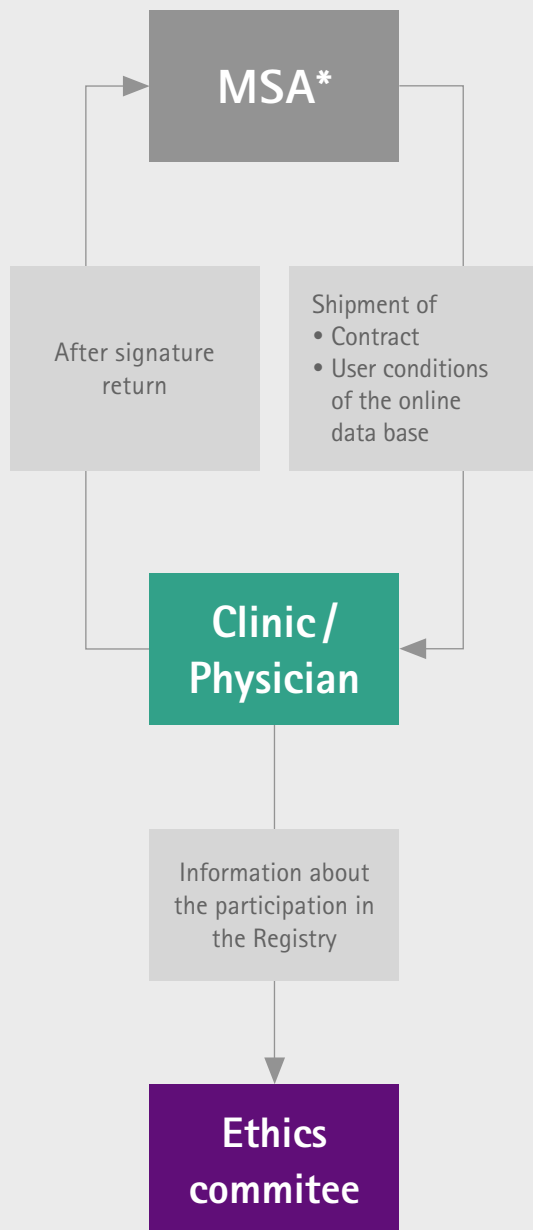


STUDY MANAGEMENT

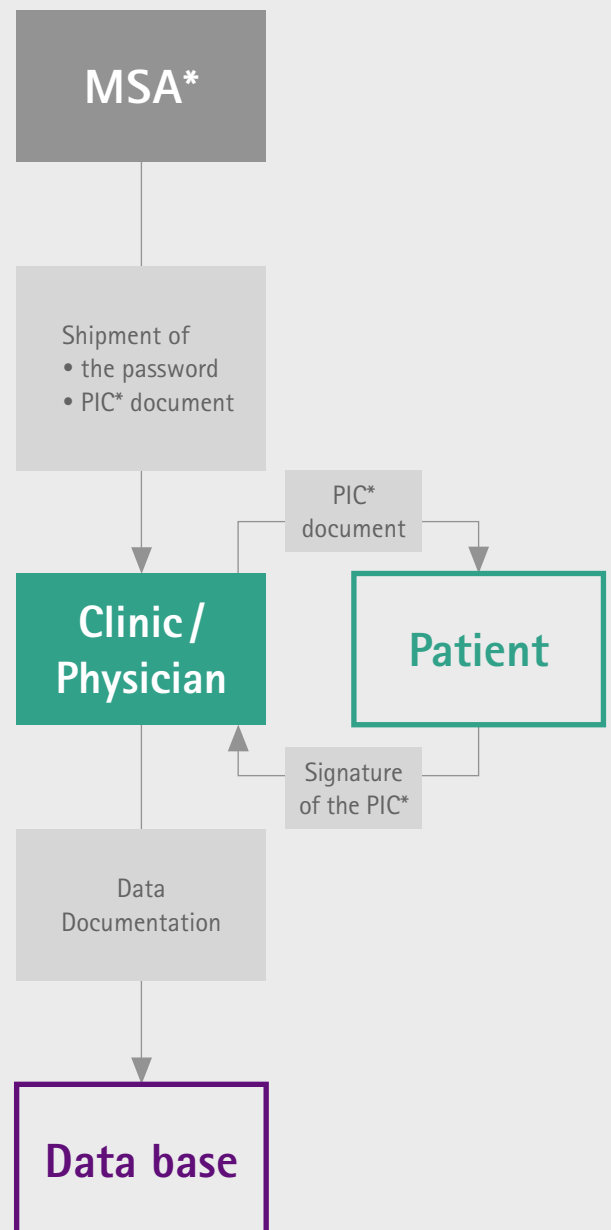
Aesculap AG
Dr. rer. nat. Petra Baumann, MBA
Medical Scientific Affairs
Am Aesculap Platz
D-78532 Tuttlingen
Phone: +49 7461-95-1646
Fax: + 49 7461-95-1655
E-mail: petra.baumann@aesculap.de

REQUIREMENTS

Step 1:



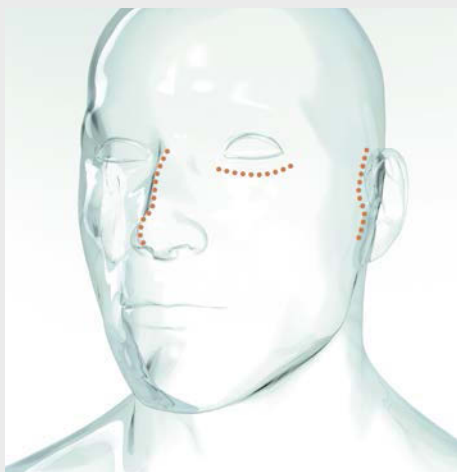
Step 2:



* MSA: Medical Scientific Affairs
PIC: Patient Informed Consent

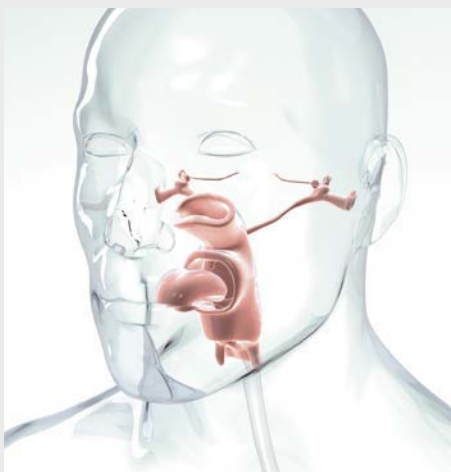
Monosyn[®] QUICK

INDICATIONS



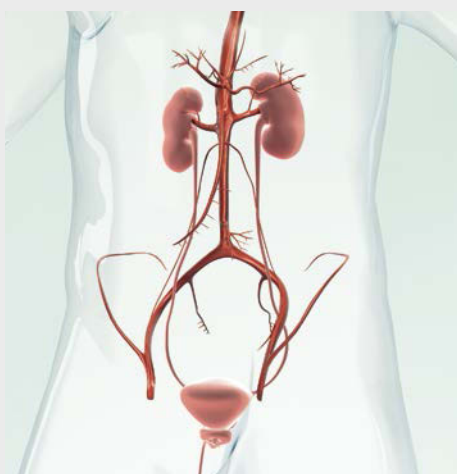
PLASTIC SURGERY

- Skin closure
- Blepharoplastias
- Lip cleft
- Periocular and oral surgery



ODONTOLOGY AND ENT

- Skin closure
- Oral mucosa



UROLOGY AND PEDIATRIC SURGERY

- Perineal closure
- Phimosis
- Hypospadias



GYNECOLOGY

- Middle or perineal episiotomies
- Soft tissue skin closure

Monosyn[®] QUICK PRODUCT REGISTRY

FAX: +49 7461 95-1655

INTEREST

If you are interested to participate in the Monosyn Quick product registry, we would like to ask you to provide us with the following details to get in touch with you. Please send your details to the following fax number.

■ ADDRESS OF THE HOSPITAL:

Name

Department

Street and No.

Zip code

Town

Country

City / Date

■ DETAILS OF THE PHYSICIAN:

First name*

Titel*

Position*

Phone No.*

Fax No.*

E-Mail*

Signature



B. Braun Surgical, S.A. | Carretera de Terrassa, 121 | 08191 Rubí | Spain
Phone +34 93 586 6200 | Fax +34 93 699 6330 | www.bbraun.com

AESCULAP® – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-2600 | www.aesculap.com

The main product trademark "Aesculap" and the product trademark "Monosyn" are registered trademarks of Aesculap AG.

Subject to technical changes. All rights reserved. This brochure may only be used for the exclusive purpose of obtaining information about our products. Reproduction in any form partial or otherwise is not permitted.