



MaiLi Data Evaluation  
PMS  
EUROPE

Status 12/2021





# Guidelines on how to use this data

## Communication via different channels

- Social media
- Homepage

## Scientific

- Scientific press
- Presentations
- Symposia
- Poster
- Prof. Ed.

## Commercial

- Hands-on training
- Marketing material
- Sales training
- Sales materials

# MaiLi post market surveillance: The real life test

## Project background



**7** countries (GER, A, BEL, ITA, SP, POR, UK)



**23** injectors



**153** treated patients (12/2021)



## Objective

- Collect experience under real life conditions
- Generate quantitative and qualitative cases

Data collected, assessment in progress

# MaiLi post market surveillance: Study design

- Experienced injectors (dermatologists and plastic surgeons) with own clinics
- Open study design – not blinded, full face
- Study period: 04/21 – 10/21
- Real aesthetic patients, no specific requirements
- 3 main indications in focus (face rejuvenation, face sculpting, lips & perioral), other indications possible acc. manufacturer recommendation
- 3 time points for feedback: injection (T0 with focus on performance & AEs), one week post injection (T1 with focus on AEs), 4 weeks post injection (T4 with focus on AEs and satisfaction)
- Identical questionnaire in every market

## Parameter

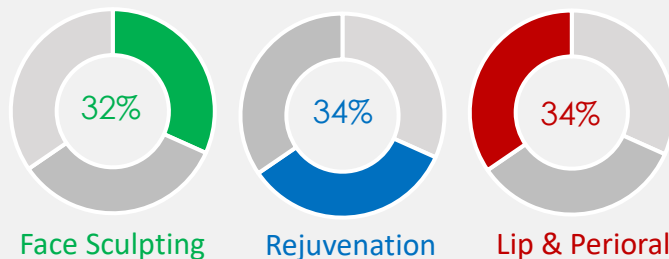
- Demographics
- Performed procedure(s)
- Product handling
- Product performance
- Satisfaction
- Adverse events

POPULATION: total 153

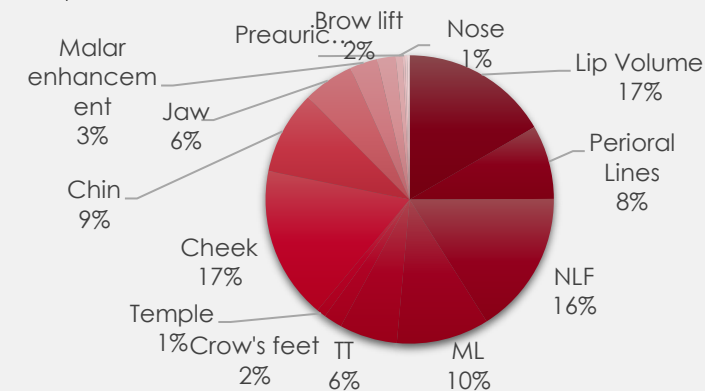


Female 88%  
Male 12%

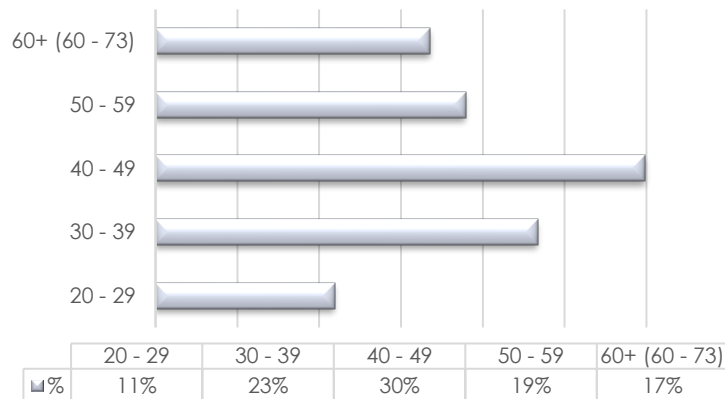
SHARE OF INDICATIONS: total 246



INJECTED FACIAL REGIONS: total 385

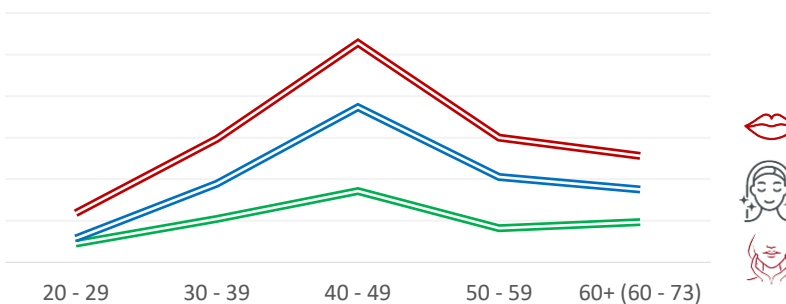


### AGE GROUPS



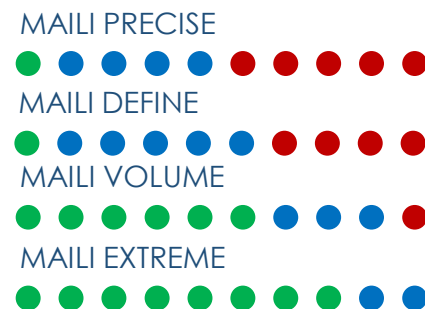
- The biggest age group are patients between **40-49** yrs old (30%).
- Youngest patients (**20-29** yrs) represent the smallest age group (11%).

### INDICATIONS PER AGE GROUP



- **Lip & Perioral** treated mainly in younger patients (**18-29**)
- **Rejuvenation** most treated indication in all age groups.
- **Sculpting** (restoration) mostly treated in **70+ yrs**
- **Sculpting** (beautification) mostly treated in the youngest age group (**18-29** yrs).

### PRODUCT UTILISATION

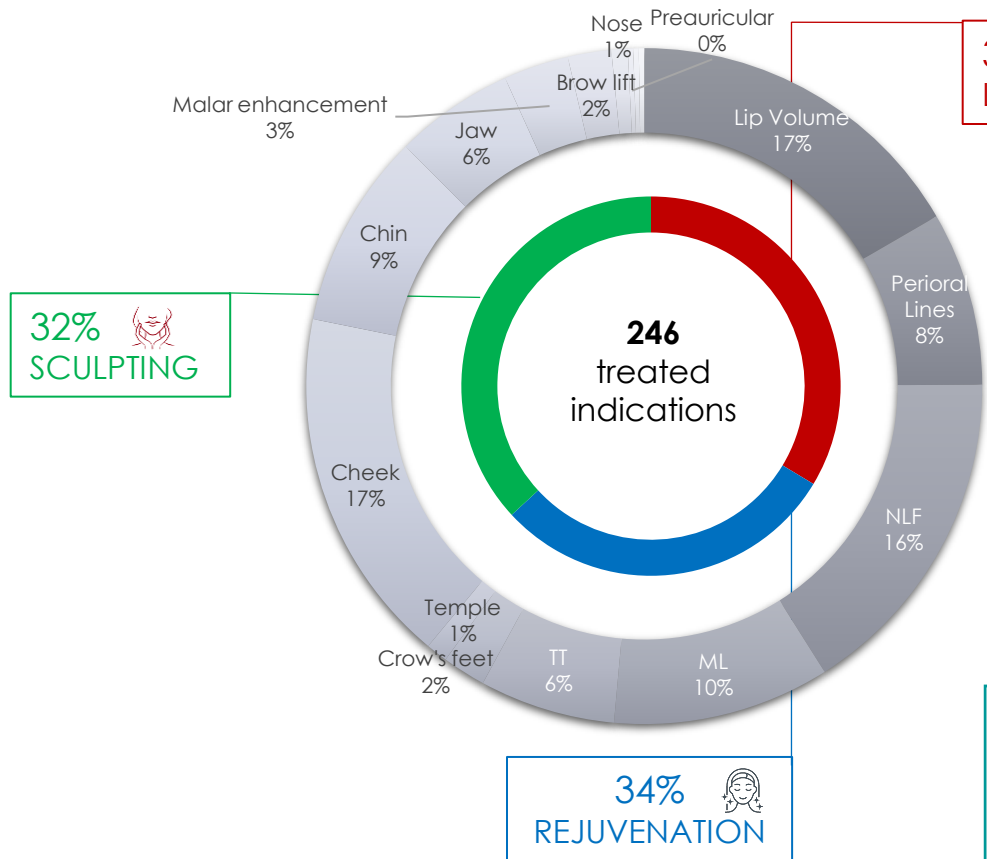


Sculping  
 Rejuvenation  
 Lip&PO

- Maili **Precise** mostly used for lips & perioral injections
- Maili **Define** mostly utilized for Rejuvenation
- Maili **Volume** mostly used in Sculping
- Maili **Extreme** is the main choice for Sculping


# Overall indications and product used

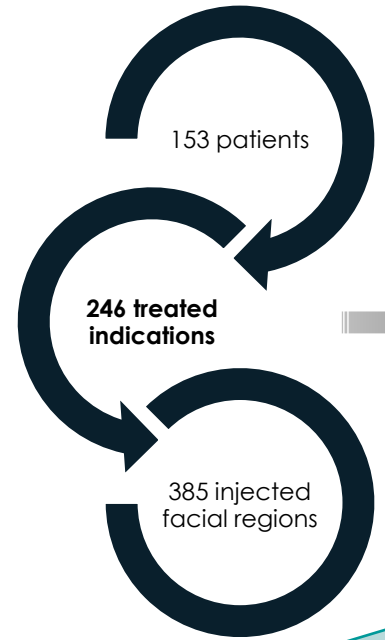
 **385 INJECTED FACIAL REGIONS**



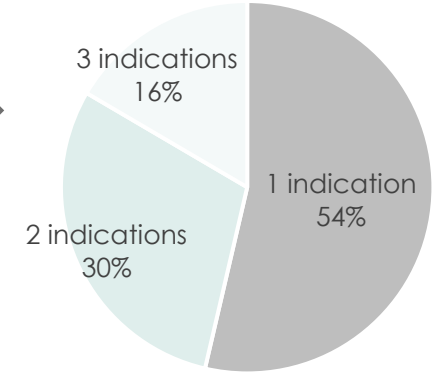
**34%**  **LIP & PERIORAL**

**32%**  **SCULPTING**

**34%**  **REJUVENATION**



**46% MULTIPLE TREATMENTS**



- The most frequently treated indication are **Lip & Perioral** and **Rejuvenation** (34 each%)
- In 46% of cases the patients are treated for **multiple indications**
- Out of 385 total injected facial regions, **Lip Volume** and **Cheek** area were the most frequently treated (17% each)

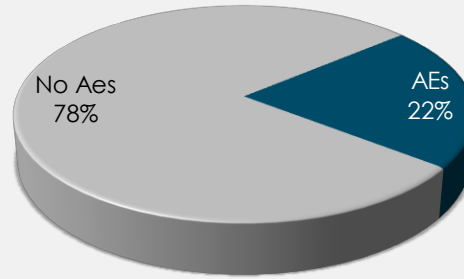
# Product Safety & Satisfaction

## POPULATION

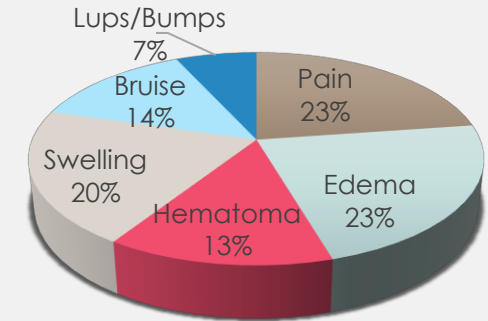


N=153  
Female 88%  
Male 12%

## COMPLICATIONS

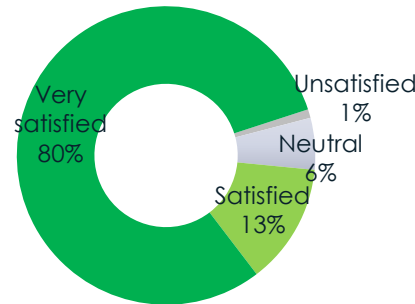


## AEs DISTRIBUTION



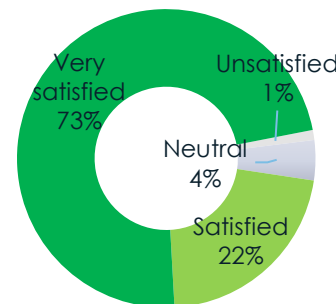
- **22%** of the cases presenting **Aes**
- **Edema** and **Pain** are the most frequent AEs (23% each)
- **97%** of physicians and patients are satisfied or very satisfied

## SATISFACTION PHYSICIANS T1 & T4



**93%**

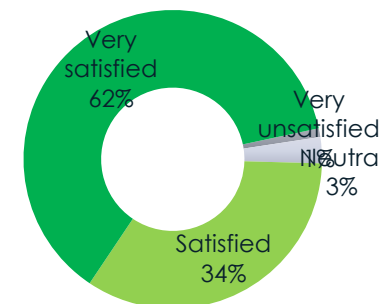
of physicians satisfied or very satisfied 1 week after treatment



**95%**

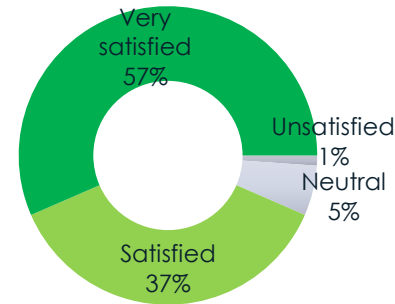
of physicians satisfied or very satisfied 4 weeks after treatment

## SATISFACTION PATIENTS T1 & T4



**93%**

of physicians satisfied or very satisfied 1 week after treatment



**94%**

of physicians satisfied or very satisfied 4 weeks after treatment

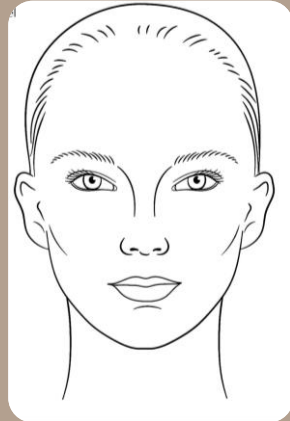
# MaiLi indications & face regions

## 3 MAIN INDICATIONS/PERFORMED PROCEDURES

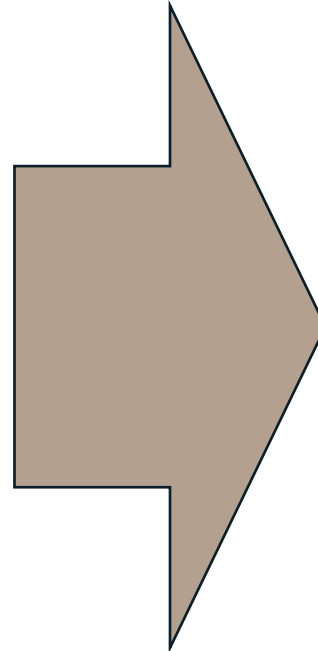
LIPS & PERIORAL  
restoration,  
contouring, enhancement

FACE REJUVENATION  
restoration

FACE SCULPTING  
Volume,  
contouring,  
shape



N = 246



## 14 INJECTED REGIONS



- Lip Volume
- Perioral Lines



- Nasolabial Folds
- Marionette Lines
- Tear Trough
- Crow's feet
- Temple

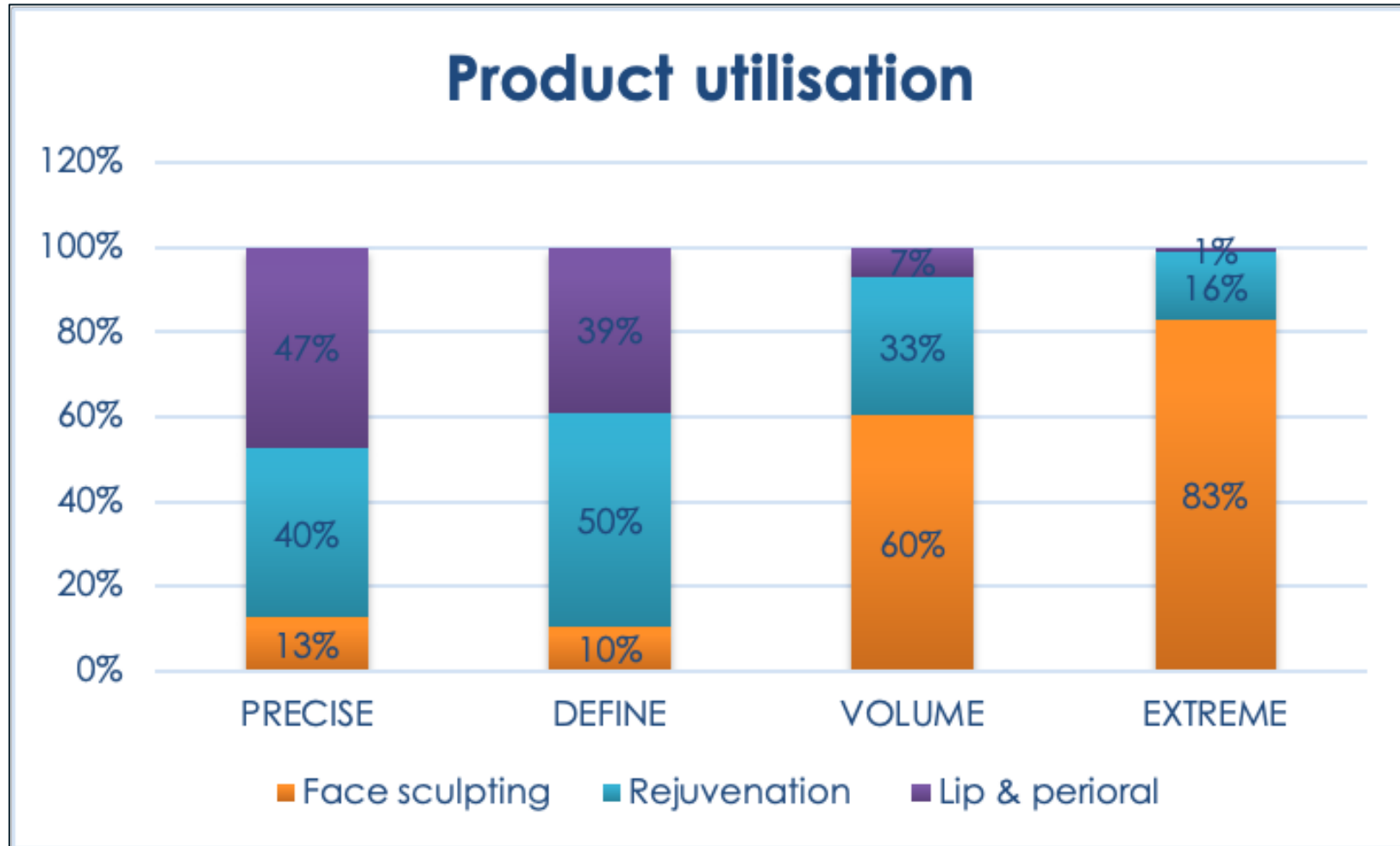


- Cheek
- Chin
- Jaw
- Malar enhancement
- Brow lift
- Nose
- Preauricular

N = 385



# Indications detail: product used by indication



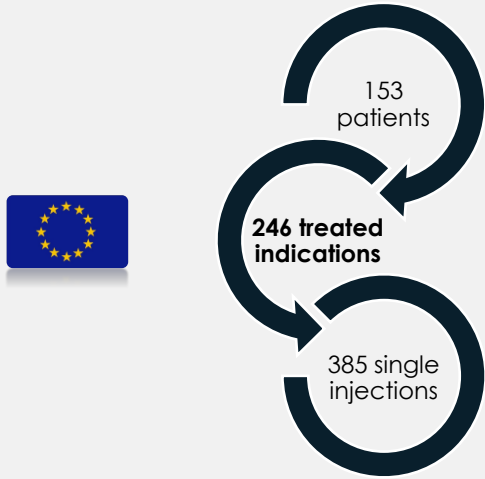
- Products have been used according the manufacturers recomendation
- MaiLi **Precise** and **Define** are the most versatile products used wether as single product or in combination to be layered

# Correlation btw product, AE, Technique, amount, depth

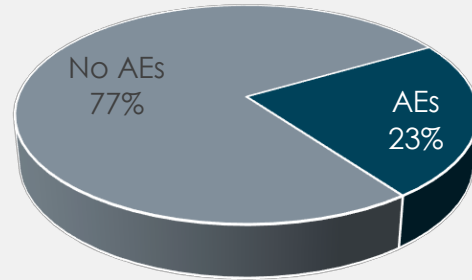
Product	Technique	No. of treatments	% treatm.	No. of AEs	% AEs	Min. inj. vol ml	Max. inj. vol ml
PRECISE	Blanching	7	4%	1	2%	0,2	0,8
	Bolus	4	2%	1	2%	0,7	1
	Fanning	5	3%	2	4%	0,7	1
	Linear	35	21%	9	18%	0,2	1
	Puncture	2	1%	0	0%	1	1
	Retrograde	1	1%	0	0%	1	1
			<b>54</b>	<b>33%</b>	<b>13</b>	<b>25%</b>	<b>0,2</b>
DEFINE	Blanching	1	1%	0	0%	0,4	0,4
	Fanning	5	3%	2	4%	0,4	1
	Linear	34	20%	12	24%	0,2	2
	Puncture	2	1%	1	2%	0,3	1
	Retrograde	7	4%	1	2%	0,5	2
			<b>49</b>	<b>30%</b>	<b>16</b>	<b>31%</b>	<b>0,2</b>
VOLUME	Bolus	26	16%	11	22%	0,1	3
	Fanning	3	2%	0	0%	0,5	0,5
	Linear	4	2%	1	2%	0,1	0,5
	Retrograde	5	3%	1	2%	0,4	3
			<b>38</b>	<b>23%</b>	<b>13</b>	<b>25%</b>	<b>0,1</b>
EXTREME	Bolus	20	12%	9	18%	0,1	1
	Fanning	4	2%	0	0%	0,3	1
	Retrograde	1	1%	0	0%	4	4
		<b>25</b>	<b>15%</b>	<b>9</b>	<b>18%</b>	<b>0,1</b>	<b>4</b>
	<b>TOTAL</b>	<b>166</b>	<b>100%</b>	<b>51</b>	<b>100%</b>		

- The highest rate of **complications** occurred when:
  - MaiLi Precise or MaiLi Define injected with **linear** technique
  - MaiLi Volume or MaiLi Extreme injected with **Bolus** technique

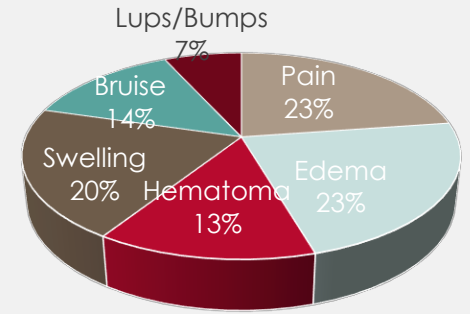
# PRODUCT SAFETY: EU + REGIONS



## ⚠️ COMPLICATIONS

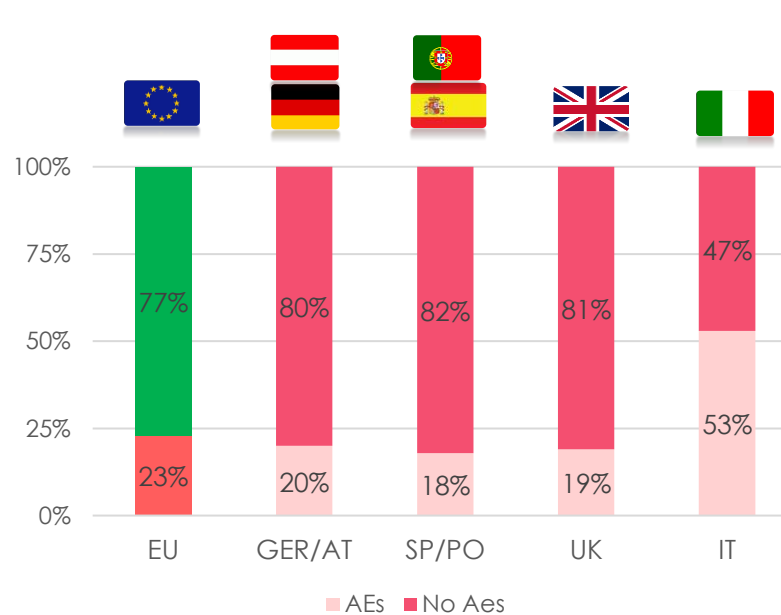


## 🩹 AEs DISTRIBUTION

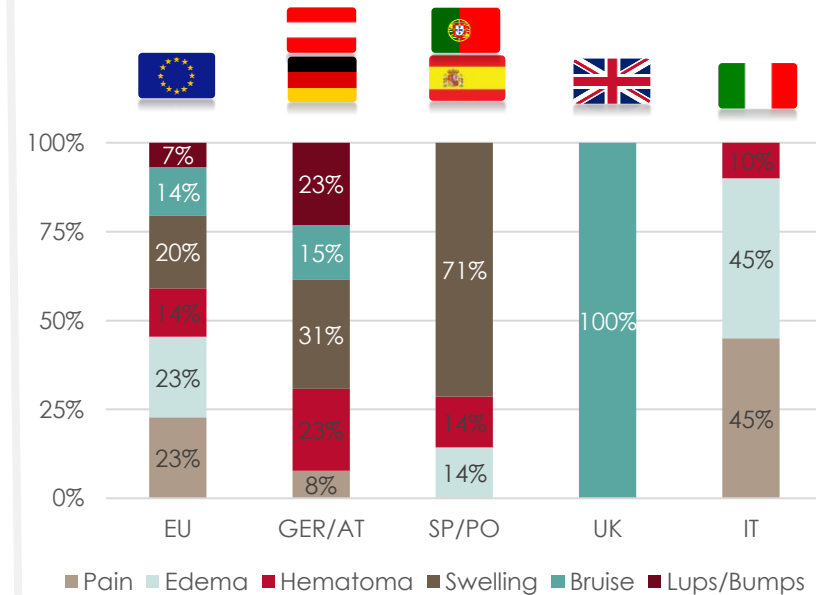


- Good product safety with **77%** of total cases presenting no AEs.
- **Pain** and **Edema** represent the most frequent AE types (23% each).
- **Italy** shows highest rate of complications (related to one specific injector)

## AEs PER REGION\*

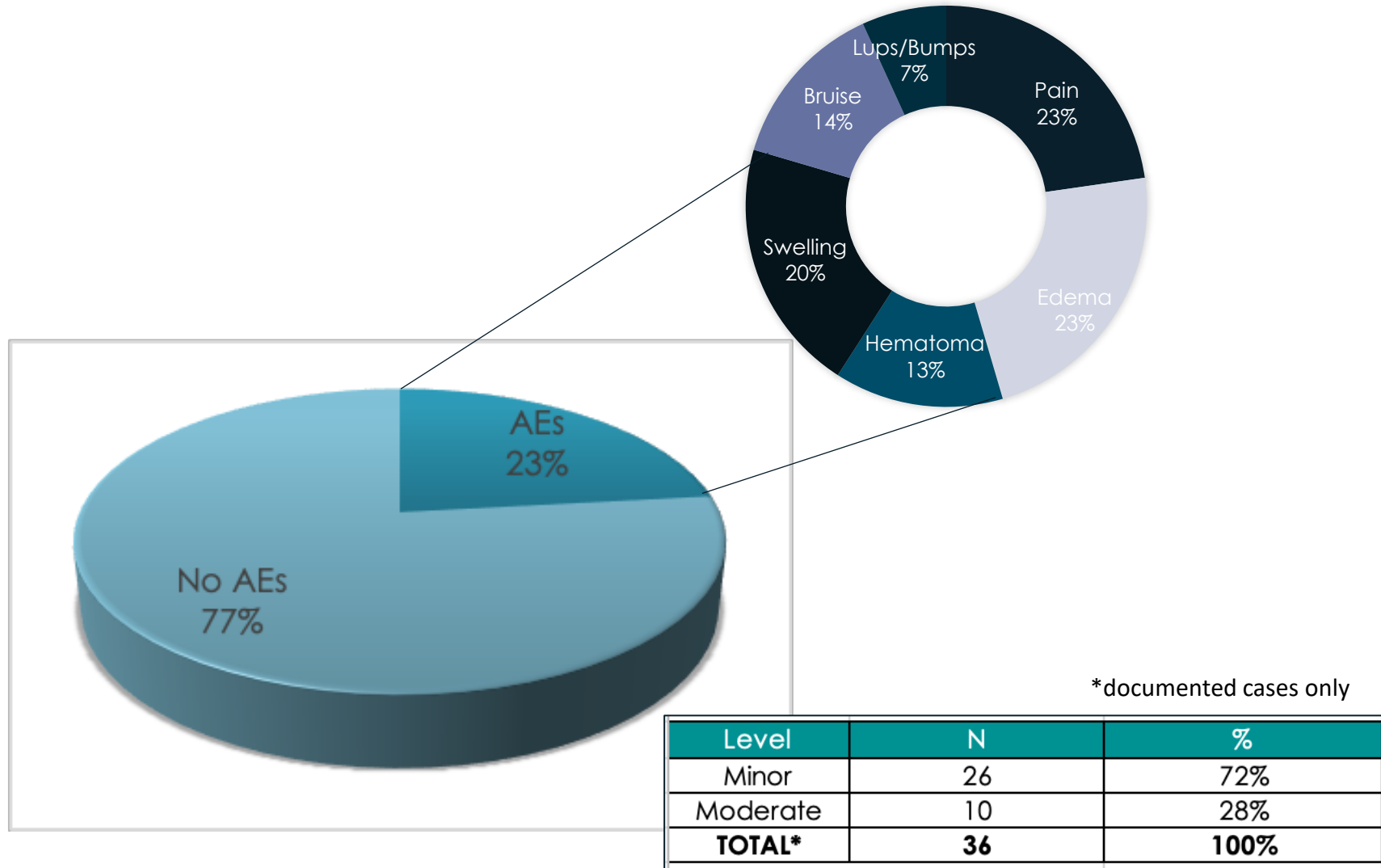


## AEs DISTRIBUTION PER REGION\*



\*No data available for Belgium

# AE\* rate & type for all indications

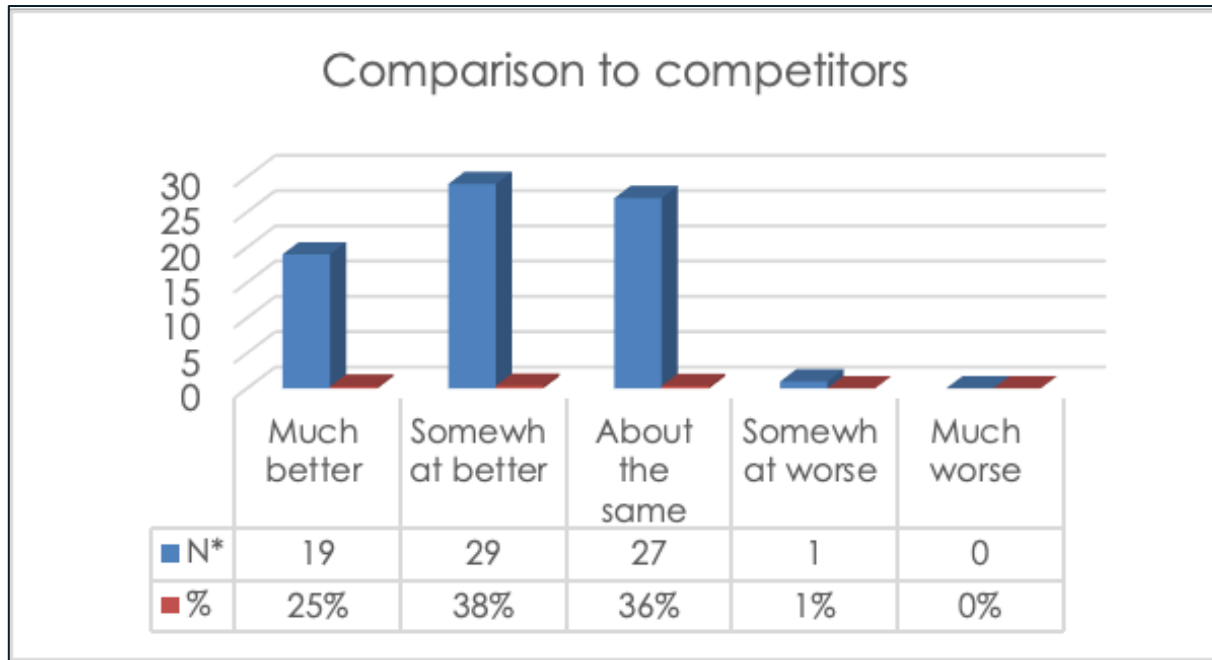


**SAFETY:  
ADVERSE EVENTS &  
COMPLICATIONS**

- High safety profile of MaiLi HA products: **77%** of performed procedures without Aes
- 72% occurred on a **MINOR** level
- **Edema** and **Pain** were the most common AEs (23% each)

# Comparison to competition

Q: COMPARED TO OUR COMPETITORS, IS OUR PRODUCT QUALITY BETTER, WORSE, OR ABOUT THE SAME?\*



\*only documented cases N = 76

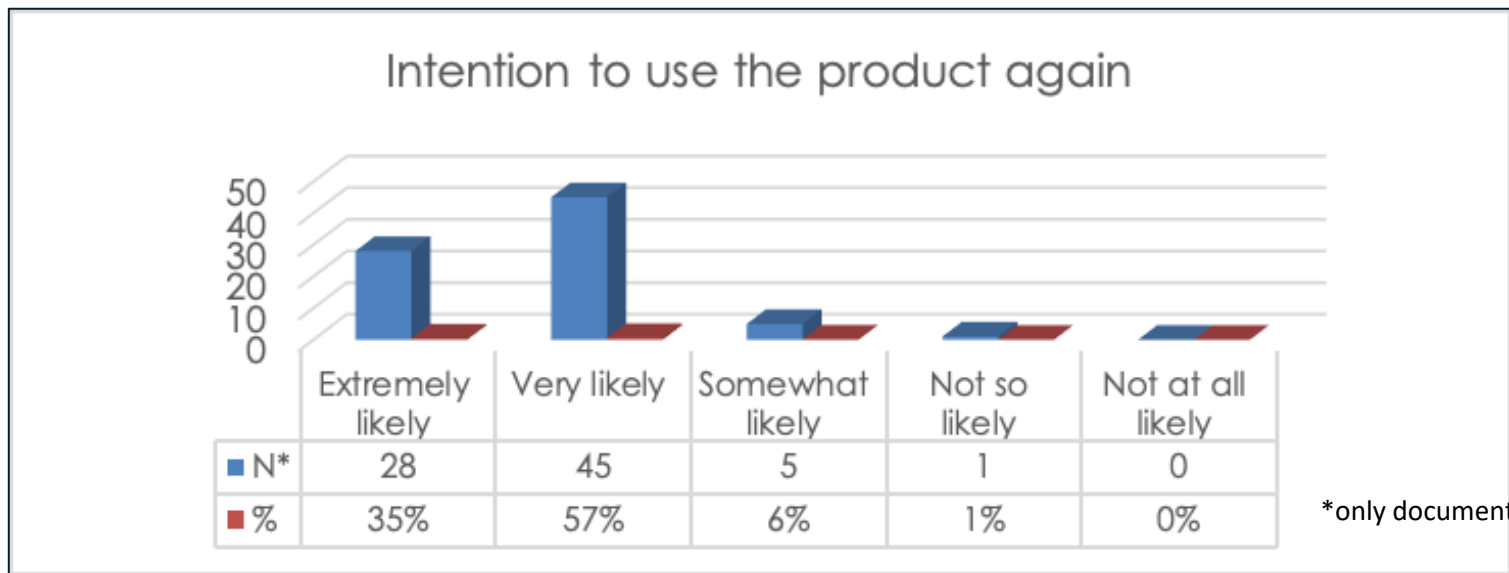
COMPARISON TO COMPETITORS EU + REGIONS					
	Much better	Somewhat better	About the same	Somewhat worse	Much worse
EU	25%	38%	36%	1%	0%
GER/AT	53%	29%	12%	6%	0%
SP/PO	24%	57%	19%	0%	0%
BE	NO DATA				
UK	NO DATA				
IT	0%	0%	100%	0%	0%

## Comparison to competitors: PHYSICIAN

- In EU consolidated cases, **63%** of physicians rated MaiLi products somewhat better or much better than competitors and 36% rated „about the same“ as competitors
- German/Austrian physicians rated MaiLi as „much better“, Iberian doctors, as „somewhat better“

# Intention to use

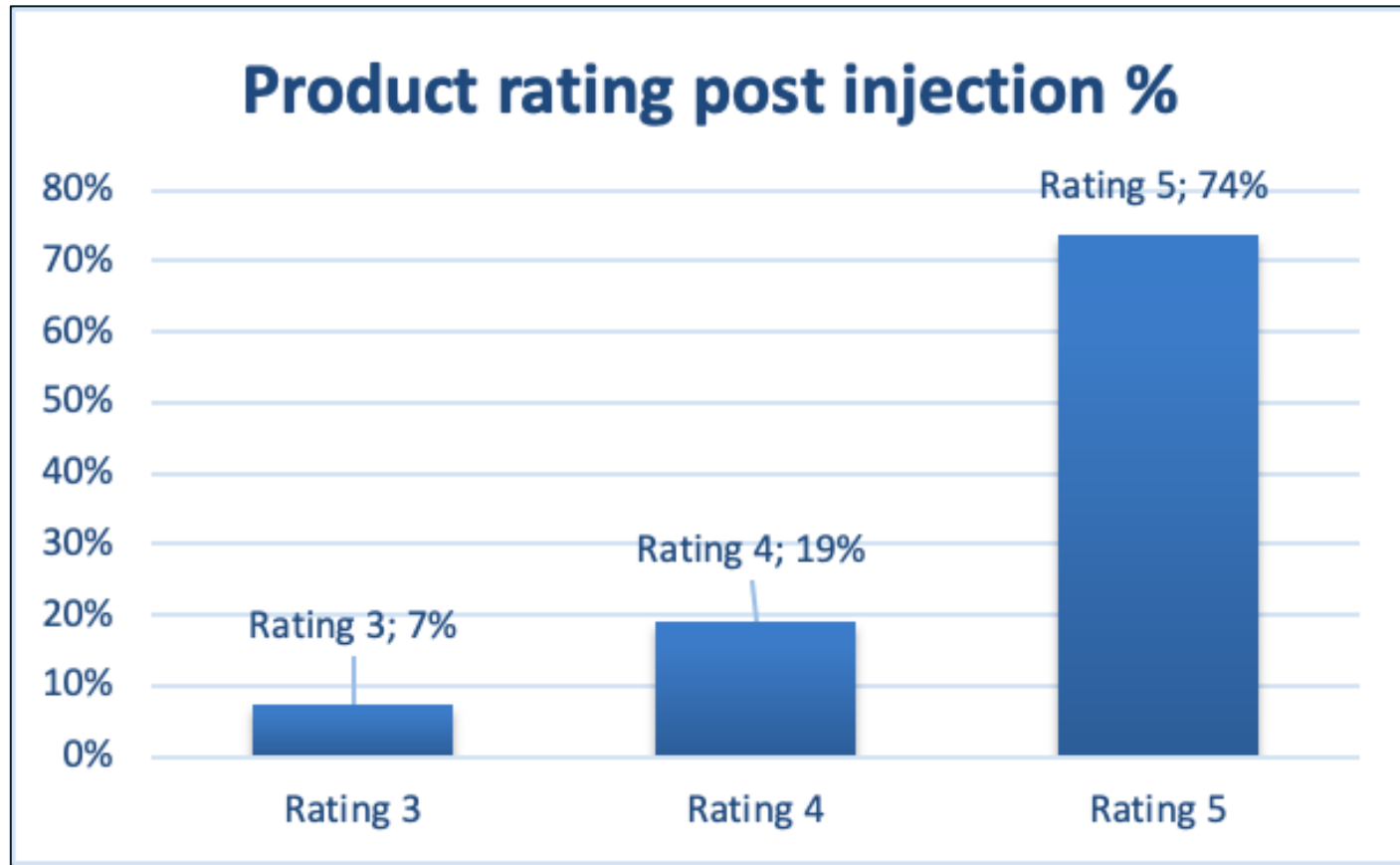
Q: HOW LIKELY WOULD YOUR CLINIC/PRACTICE BE TO USE PRODUCT?\*



➤ **93%** of european physicians have the intention to use MaiLi products „extremley likely“ or „very likely“

INTENTION TO USE AGAIN EU + REGIONS					
	Extremely likely	Very likely	Somewhat likely	Not so likely	Not at all likely
<b>EU</b>	35%	57%	6%	1%	0%
<b>GER/AT</b>	41%	53%	0%	6%	0%
<b>SP/PO</b>	47%	42%	11%	0%	0%
<b>BE</b>	NO DATA				
<b>UK</b>	NO DATA				
<b>IT</b>	0%	100%	0%	0%	0%

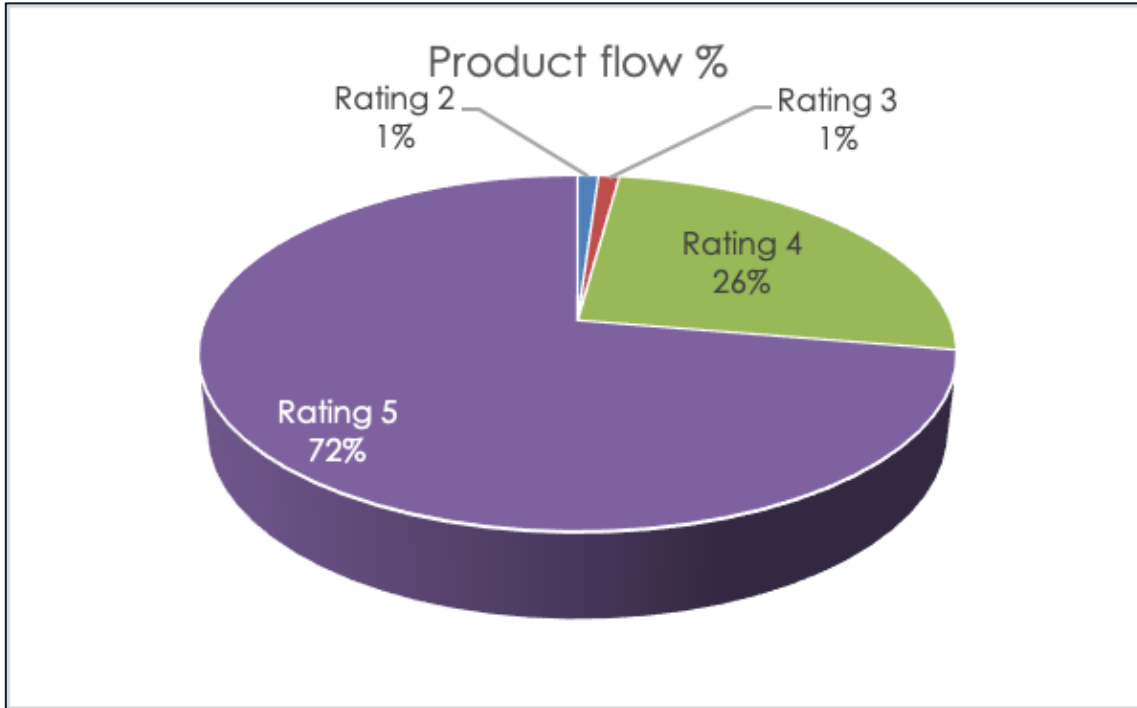
# Overall product rating



only documented cases N=95 patients, cases with no answer are not included

➤ **93%** of physicians give MaiLi dermal fillers an overall top rating of „very good“ (5) and „good“ (4)

# Product flow

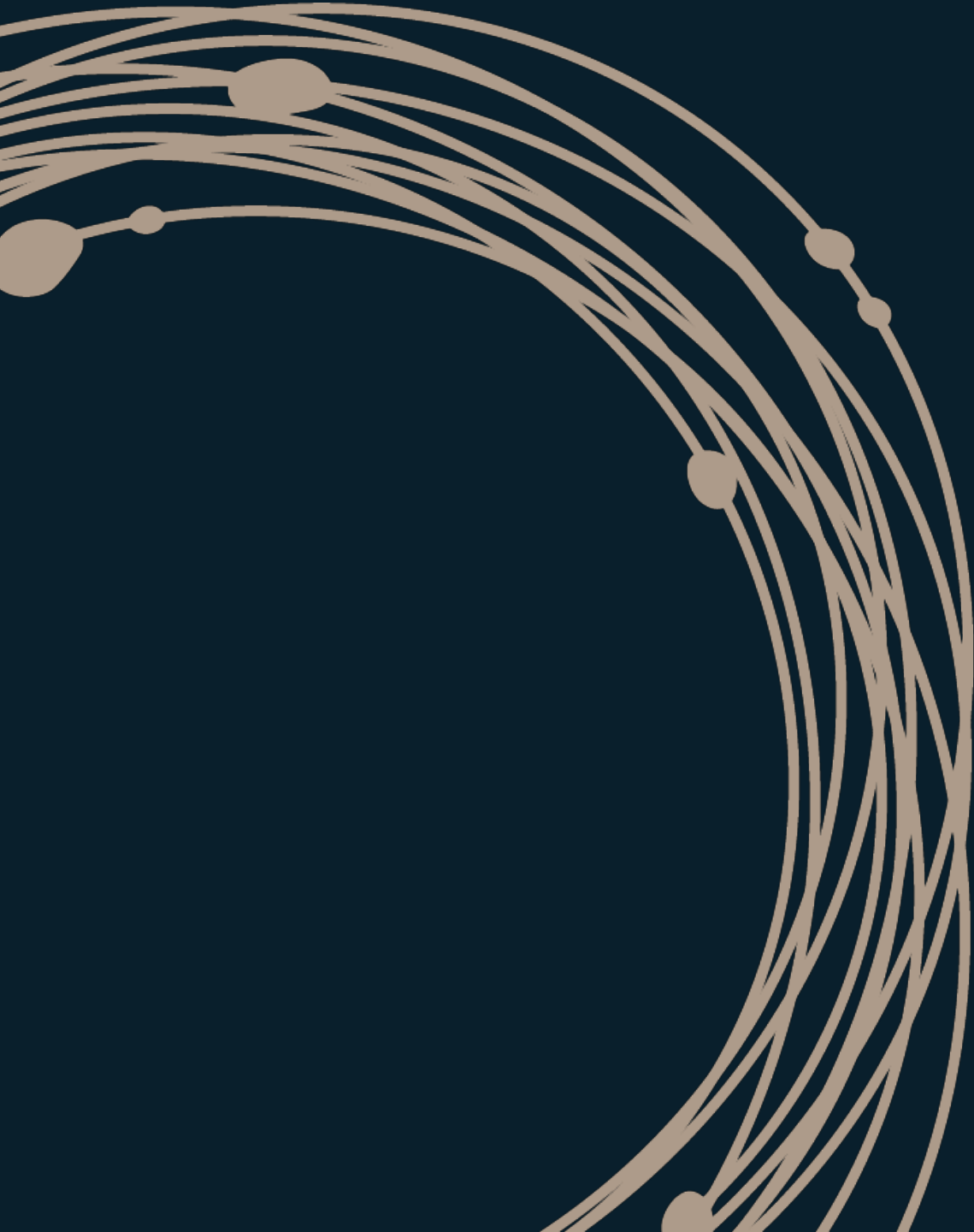


➤ **98%** of physicians rate the product flow in the tissue as very good (5) or good (4)

Rating	N*	%
Rating 2	1	1%
Rating 3	1	1%
Rating 4	24	26%
Rating 5	68	72%
<b>TOTAL</b>	<b>94</b>	<b>100%</b>

only documented cases N=94, cases with no answer are not included, all product types and injected facial regions included

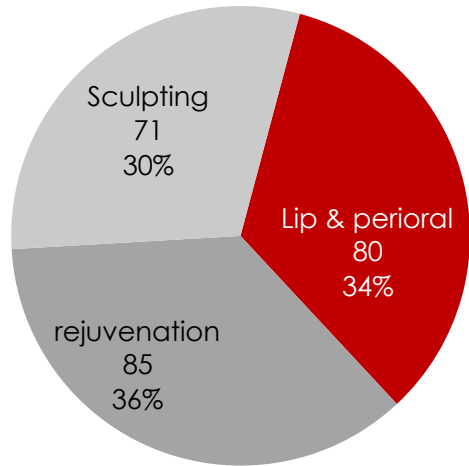




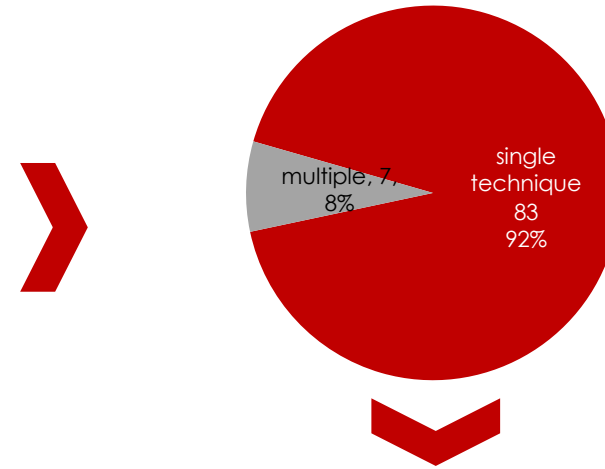
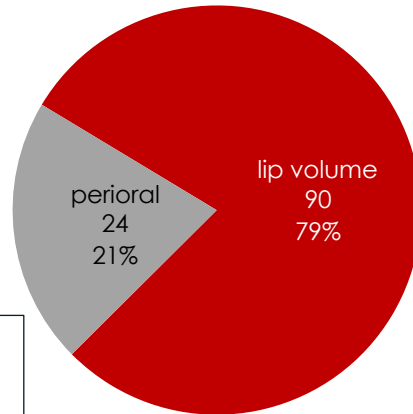
# Lips & perioral

Subgroup Lip volume

# Product and injection technique types associated with AE in the subgroup lip volume single technique



The **lip & perioral (80)** procedures were performed with **114 single injections** (multiple injections to use different products or techniques)

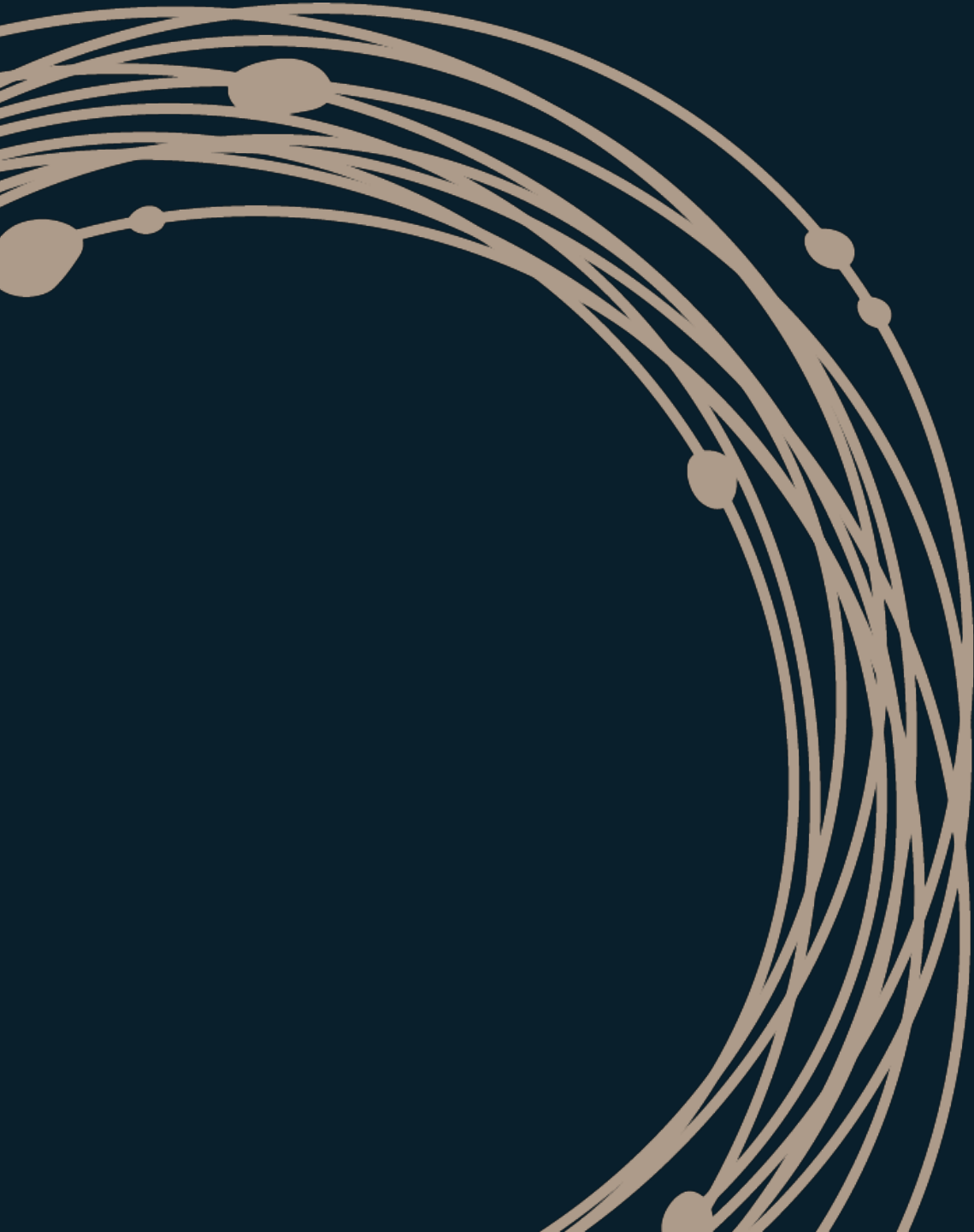


In the subgroup of lip volumizing (79 %) using one injection technique (92%).

Usage of DEFINE with **linear** technique (47%) was associated with the highest rate (55%) of AEs.

The second highest AE rate (18%) was seen at usage of DEFINE with **fanning** and PRECISE with **linear** respectively.

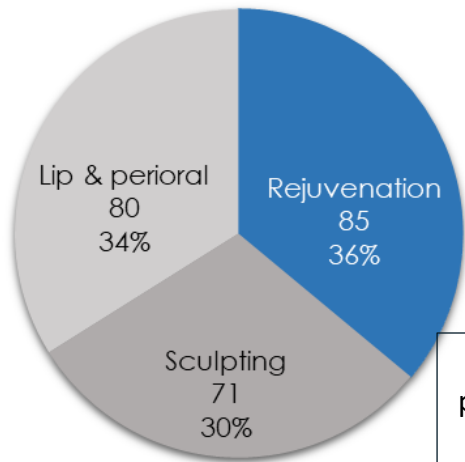
Product	Technique	No. of treatments	% treatm.	No. of AEs	% AEs	Min. inj. Vol. ml	Max. inj. vol.ml
PRECISE	Linear	23	32%	6	18%	0,4	1,4
	Bolus	2	3%	0	0%	0,3	0,6
	Fanning	1	1%	1	3%	1	1
		<b>26</b>	<b>36%</b>	<b>7</b>	<b>21%</b>	<b>0,3</b>	<b>1,4</b>
DEFINE	Linear	34	47%	18	55%	0,4	1,4
	Bolus	2	3%	1	3%	0,2	1
	Fanning	4	5%	6	18%	0,7	1
	Puncture	2	3%	0	0%	1	1
	<b>42</b>	<b>58%</b>	<b>25</b>	<b>76%</b>	<b>0,2</b>	<b>1,4</b>	
VOLUME	Linear	1	1%	1	3%	0,6	0,6
	Bolus	2	3%	0	0%	0,6	1
	Puncture	2	3%	0	0%	/	/
		<b>5</b>	<b>7%</b>	<b>1</b>	<b>3%</b>	<b>0,6</b>	<b>1</b>
<b>TOTAL</b>		<b>73</b>	<b>100%</b>	<b>33</b>	<b>100%</b>		



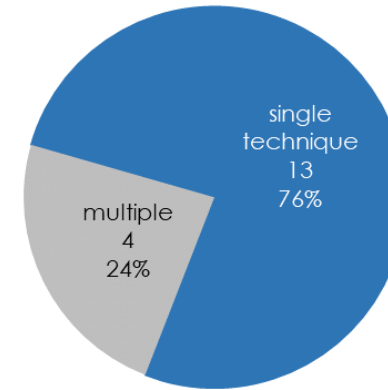
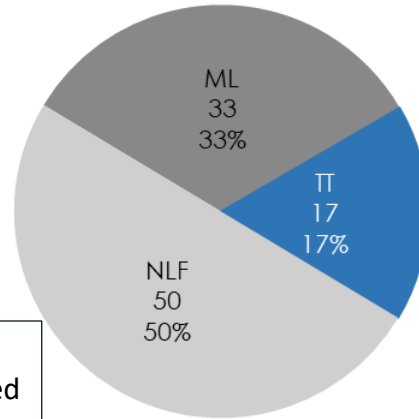
# Rejuvenation

Subgroup Tear through

# Product and injection technique types associated with AE in the subgroup tear trough single technique



The **rejuvenation (85)** procedures were performed with **100 single injections** (multiple injections to use different products or techniques)



In the subgroup of tear trough (17 %) using one injection technique (76%).

Usage of PRECISE with **bolus** technique (15%) was associated with the highest rate (60%) of AEs.

The second highest AE rate (20%) was seen at usage of PRECISE with **fanning** and DEFINE with **linear** respectively.

No AEs have been seen with the usage of VOLUME in tear trough.

Product	Technique	No. of treatments	% treatm.	No. of AEs	% AEs	Min. inj. vol ml	Max. inj. vol ml
PRECISE	Linear	5	38%	0	0%	0,5	1
	Bolus	2	15%	3	60%	N/A	N/A
	Fanning	1	8%	1	20%	1	1
		<b>8</b>	<b>62%</b>	<b>4</b>	<b>80%</b>	<b>0,5</b>	<b>1</b>
DEFINE	Linear	1	8%	1	20%	1	1
		<b>1</b>	<b>8%</b>	<b>1</b>	<b>20%</b>	<b>1</b>	<b>1</b>
VOLUME	Linear	1	8%	0	0%	0,7	0,7
	Bolus	3	23%	0	0%	0,4	0,8
		<b>4</b>	<b>31%</b>	<b>0</b>	<b>0%</b>	<b>0,4</b>	<b>0,8</b>
<b>TOTAL</b>		<b>13</b>	<b>100%</b>	<b>5</b>	<b>100%</b>		

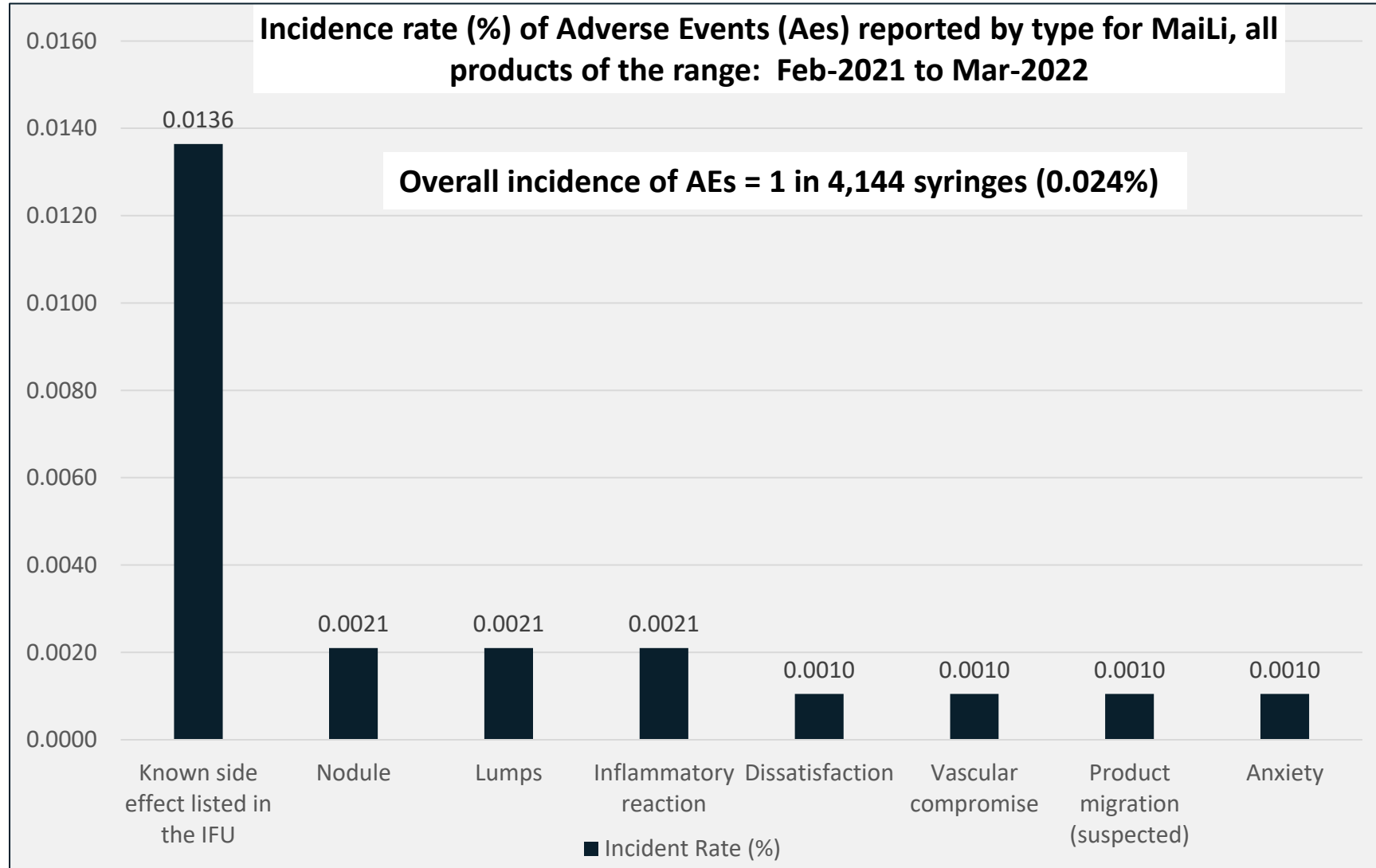


# MaiLi 1 Year Safety Profile

Feb 2021 – Mar 2022

## MaiLi Safety Profile (all SKUs): Feb-2021 to Mar-2022

- Evidence to indicate the safety of MaiLi in use was collated from Post-Market Surveillance and product distribution worldwide.
- No product defects were found to be responsible for any AE reported to Sinclair.
- No treatment discontinuation due to a product related issue following an Adverse Event report.
- Known side effects includes redness/ swelling/ pain etc. that can occur shortly after injection and are usually temporary.
- One case of vascular compromise was reported with the root cause confirmed as user error.
- No events were assessed as reportable to the Competent Authorities.



**Thank you** | MAILI