# Orthopaedic Implant Labeling – how small is too small? Preventing a Never Event

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**Research article**

**Keywords:** Implant label, never event, patient safety

**Posted Date:** October 22nd, 2019

**DOI:** https://doi.org/10.21203/rs.2.16347/v1

# Abstract

Background There are currently no guidelines for the standards of legibility, dimensions and presentation on implant labels. There have been recommendations that text height on implant boxes should be at least 4mm. Orthopaedic implants are packaged individually and checked intraoperatively once the correct size has been identified. During this process there are many factors that could lead to error. Dimensions of laminar flow canopies fixes the distance at which the implant label can be read from. Never events are multifactorial. Small text, poor vision due to liquid on a surgeons visor and the seam of the plastic packaging can obscure vital information and contribute to a never event.

Methods We reviewed elective and trauma implants. Using the National Joint Registry 15th Annual Report we identified the most commonly used total hip and knee arthroplasty implants (4 hip and 3 knee). We also reviewed the femoral nail and plate implants of 3 commonly used implant companies. Implant box text size was compared to a theoretical minimum standard of 4mm for text on implant labels derived from Snellen Chart Formula.

Results 20 implants were reviewed (hip – 8, knee 6, trauma-6). Across all implants, the average implant size text height was 2.8mm. The average for trauma and elective implants was the same. The average expiry date is 2mm in height. On 65% (13/20) of implant boxes, the plastic wrapping seam obscured vital text. 15% (3/20) of boxes had a text height of 4mm.

Conclusion The recommended text height is 4mm. This was observed in only 15% of implants. Never events are usually multifactorial however, occur in part due to poor legibility of implant labels leading to incorrect implants being inserted. To further progress these recommendations, manufacturers can consider and adopt these suggestions to reduce risk and improve patients' safety when their implants are being used.


# 1 Background

Orthopaedic surgical implants are boxed individually and upon deciding on the required implant or size, a member of theatre staff locates the implant from the inventory and show the scrub nurse and operating surgeon pertinent information on the box. Once checked, the implant can be opened. There are several reasons for this process, including ensuring the correct implant has been selected, the correct size and the implant is in date. The quality of packing varies and often there can be difficulties seeing and reading the required information due to the size of text and the reflective clear plastic wrapping. The seam on the plastic wrapping is often over a crucial piece of information, obscuring its view and

possibly more importantly the actual size of the text is small to see clearly from a distance. [1]

Never events unfortunately do occur and wrong implant and prosthesis are number two on NHS Improvements 2018 list. [2] Orthopaedic surgeons and theatre staff therefore need to be cognoscente of this and ensure implant boxes are checked thoroughly before use and implantation. There continues to be instances where the incorrect implant or incorrect size of implant is used. The reasons for this are multifactorial but undoubtedly poor presentation of packaging; visibility and legibility of implant boxes contribute to a never event as described by Adrian Jones.[3]

Laminar flow ventilation is used for arthroplasty surgery to reduce airborne bacterial load as one component of infection reduction.[4-5] Along with this appropriate clothing and a reduction in movement throughout theatre further reduce infection. Studies have shown that movement of unscrubbed theatre staff into the laminar flow canopy creates turbulence; disturbing airflow potentially creating an unfavourable microbiological environment around the surgical site.[5] This occurs when attempting to overcome the issues of poor visualisation of the implant box label. The implant box is moved closer to the surgical teams eyes which may result in the packing being held over sterile trays by a bare unscrubbed arm increasing the risk of infection transmission or having the surgeon move to the periphery of the laminar flow and read the label disrupting the flow of the surgical procedure.[6]

A literature search by the authors has revealed there are no clear, concise guidance and no consensus on the appropriateness of orthopaedic implant labeling. The most common hip and knee arthroplasty implants were identified using the National Joint Registry 15$^{th}$ Annual Report 2018.[7] This paper aims to highlight the lack of guidance. The authors aim to offer guidance on the appropriateness of orthopaedic implant labeling, improving

legibility and allowing simpler identification. The aim of this is to reduce the risk of a never event.

## 2 Methods

Prospectively examined the boxes of orthopaedic implants for elective and trauma surgery. We reviewed the most commonly used implants within our region. Elective implants most commonly used on the National Joint Registry were selected– hip (femoral and acetabular) and knee (femoral and tibial). Trauma implants included– femoral nail and plate. We reviewed implants from the main orthopaedic implant companies for trauma. Implants for elective surgery were those most commonly used in the National Joint Registry. The implants reviewed are those commonly used in orthopaedic surgery within our region.

The parameters assessed were dimensions of the box, text height and width of the implant size and expiry date and location of the plastic seal on the outer wrapping.

Measurements were made using a flat paper ruler, which is in current surgical use. An average was taken if the word contained upper and lower case letters.

## 3 Results

The authors measured the dimensions of commonly used orthopaedic implant boxes. On these boxes, we measured the height and width of the box face that contains information pertinent to size and expiry date. We then measured the height and width of the implant size and expiry date text. We also identified the position of the plastic seal on the outer wrapping and identified this as being positioned in either the upper, middle or lower third and the significance of this.

The authors reviewed the implant boxes of the four most commonly used femoral stems.

Table 1. Total Hip Replacement – femoral implant

Table 1

| Femoral Implant/Dimensions | 1 | 2 | 3 | 4 | Mean height (cm) |
|---|---|---|---|---|---|
| Box (cm) | 16x6 | 16x6 | 15x5 | 15x5.5 | 5.6 |
| Implant size (cm) | 1x0.4 | 1.7x0.4 | 1.4x0.3 | 0.4x0.2 | 0.3 |
| Expiry date (cm) | 0.8x0.2 | 1.3x0.2 | 1.9x0.2 | 1.4x0.2 | 0.2 |
| Plastic seal | middle | middle | middle | upper | |

The authors reviewed the implant boxes of the four most commonly used acetabular components:

Table 2. Total Hip Replacement – acetabulum implant

Table 2

| Acetabular Implant/Dimensions | 1 | 2 | 3 | 4 | Mean height (cm) |
|---|---|---|---|---|---|
| Box (cm) | 12x6 | 14.5x8.5 | 14.5x8.5 | 14.5x8.5 | 7.8 |
| Implant size (cm) | 1.6x0.3 | 1.3x0.2 | 1.3x0.2 | 1.3x0.3 | 0.25 |
| Expiry date (cm) | 1.3x0.2 | 1.7x0.2 | 1.7x0.2 | 1.7x0.2 | 0.2 |
| Plastic seal | upper | middle | middle | upper | |

The mean height of the implant box was 5.6 cm for femoral component and 7.8cm for acetabular components. The mean height of the implant size text of total knee replacement femoral and acetabular component boxes was 3mm.  The mean height of the expiry date text was 2mm on femoral implant boxes and 3mm on acetabular implant boxes.

The authors reviewed the implant boxes of the three most commonly used total knee replacement femoral components:

Table 3. Total Knee Replacement – femoral implant

Table 3

| Femoral implant/dimensions | 1 | 2 | 3 | Mean height (cm) |
|---|---|---|---|---|
| Box (cm) | 13x7 | 13x6 | 13.5x7 | 6.6 |
| Implant size (cm) | 1.5x0.3 | 1.5x0.3 | 1.5x0.3 | 0.3 |
| Expiry date (cm) | 1.7x0.2 | 1.0x0.2 | 1.50.2 | 0.2 |
| Plastic seal | upper | middle | upper | |

The authors reviewed the implant boxes of the three most commonly used total knee replacement tibial components:

Table 4. Total Knee Replacement – tibial implant

Table 4

| Tibial implant/dimension | 1 | 2 | 3 | Mean height (cm) |
|---|---|---|---|---|
| Box (cm) | 13x7.5 | 14x7.5 | 13.7.5 | 7.5 |
| Implant size (cm) | 1.3x0.3 | 1.5x0.4 | 1.5x0.3 | 0.3 |
| Expiry date (cm) | 2.0x0.3 | 2.0x0.3 | 1.8x0.3 | 0.3 |
| Plastic seal | middle | middle | middle | |

The mean height of the box was 6.6cm for the femoral component and 7.5cm for the tibial component. The mean height of the implant size text of total knee replacement femoral and tibial component boxes was 3mm.  The mean height of the expiry date text was 2mm on femoral implant boxes and 3mm on tibial implant boxes.

Trauma implants were reviewed.

Table 5. Femoral nail

Table 5

| Femoral nail/dimensions | 1 | 2 | 3 | Mean height (cm) |
|---|---|---|---|---|
| Box (cm) | 7.5x3 | 9x3 | 7.5x3 | 3 |
| Implant size (cm) | 3x0.3 | 0.4x0.4 | 0.3x0.3 | 0.3 |
| Expiry date (cm) | 2.2x0.2 | 1.0x0.2 | 1.0x0.2 | 0.2 |
| Plastic seal | middle | middle | middle | |

The mean height of the femoral nail boxes was 3cm. The mean height of the implant size text was 3mm. The mean height for the expiry date text was 2mm.

Table 6. Femoral Plate

Table 6

| Femoral Plate/dimensions | 1 | 2 | 3 | Mean height (cm) |
|---|---|---|---|---|
| Box (cm) | 7.5x3 | 9x3 | 8x3 | 3 |
| Implant size (cm) | 1.4x0.3 | 2.3x0.3 | 2x0.3 | 0.3 |
| Expiry date (cm) | 0.9x0.2 | 0.9x0.2 | 0.9x0.2 | 0.2 |

The mean height of the femoral plate boxes was 3cm. The mean height of the implant size text was 3mm. The mean height for the expiry date text was 2mm. 0.3mm height.

On the same boxes we reviewed the position of the outer packaging plastic seam to see if it affected the visualisation of the required information. The seam was in the middle third of the box on 75% (15/20) boxes and in the upper third of the box in 25% (5/20). This led to obscuring of vital information in 75% of cases.

## 4 Discussion

It has been demonstrated here that often despite the size of the box – the actual size of the text important to the surgeon and scrub team is small. This can lead to serious consequences of the wrong size implant being opened, an implant that has expired being

opened which ultimately lead to never events. Haene et al in their (2009) article recommend the following as a standard for orthopaedic implant packaging:

1. A separate label on one side of the pack containing only the following information: implant description; a graphic (photograph or clear line drawing); implant side; implant size; expiry date; and matching component dimensions.

2. The following standards should be observed: text height should be a minimum of 4 mm; information should be presented in one language only; good visual contrast should exist between text colour and background colour (ideally black text on a white background); information should not be repeated on the same label; and the seams or folds of transparent outer sleeves should not obscure the label.

3. Larger text size need not automatically require larger labels or even larger implant boxes. Labels can be kept at an acceptable size by de-cluttering the information, as de-cluttering will improve visual acuity by increasing the clear space surrounding the letters or digits. This can be achieved by presenting the following information else- where on the box: manufacturer’s address; sterilising information; proprietary and legal notices; reference numbers; and barcodes.

From the authors’ experience and results shown above, this has not been adhered to and implant labeling does not follow the above recommendations certainly for the parameters that we investigated. The mean size of text is 3mm despite recommendations that 4mm should be the minimum text height. Patient safety and risk management are the underpinning principles of ensuring orthopaedic implants are labeled appropriately so that intraoperative checks can be performed safely without disrupting the flow of surgery.[3]

The size of text particularly for the expiry date is 2mm in height. This is extremely small text to be read at any distance. Through single-eye testing conditions, using a Snellen chart formula and 20/20 visual acuity, 3mm is the recommended minimum height for text to be legible at a distance of seven feet.[8] In standard circumstances, surgeons will use binocular

vision, which improves the visual acuity upto 15%.[9] There are several factors, which collectively could affect visual acuity to varying degrees between individuals. These factors include:

1. Most surgeons performing arthroplasty and many perform trauma wearing surgical gowns either containing a plastic visor or with a mask containing a visor which creates a distortion of light.
2. Operating light glare reflecting back off plastic visors can affect a surgeon's vision.
3. Fluid droplets on plastic visors
4. Crowding of letters and numbers
5. Time for adjustment from looking at objects under bright operating lights to areas of lower light outside the operating field

The authors are orthopaedic surgeons and appreciate that they are neither experts in ergonomics nor ophthalmologists. There is research, however, showing that a minimum of 4mm text height for the purposes of implant packaging is advisable. There is also research to show that using crowded and spaced visual acuity charts has an affect of legibility.[1,3,8-10] Text, which is larger and more spaced, so the label is not crowded, is associated with more accurate legibility.[10]

Based on the recommendations from Haene et al for packaging and Hellier et al for legibility this study confirms that there has been no improvement in visibility and legibility of implant labeling to enable the scrub nurse or operating surgeon to read labels more readily. There are still instances of never events in relation to wrong size implants and expired implants being used which in part is due to poor legibility and also the plastic seam affecting pertinent information on labels. [3]

## 5 Conclusion

We propose that orthopaedic implant companies adhere to the following minor improvements, which will improve legibility of implants labels and improve patient safety.

The recommendations are as follows:

1. A label with adequate space for the required information so there is no crowding of letters and numbers therefore larger labels are not required
2. The height of the smallest text should be no less that 4mm, with no interference of the plastic seam obscuring the information.

As mentioned the limitations of this study are that the authors are neither ophthalmologists nor experts in ergonomics, however, experts in these fields based the recommendations suggested on research. To further progress these recommendations, manufacturers can consider and adopt these suggestions to reduce risk and improve patients' safety when their implants are being used.

## Declaration

- Ethics approval and consent to participate – not applicable
- Consent for publication – not applicable

- Availability of data and materials - The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request
- Competing interests – The authors declare that they have no competing interests
- Funding – not applicable
- Authors' contributions – BK and GK contributed to the design, research, analysis and write up of this manuscript. Both authors read and approved the final manuscript.
- Acknowledgements – not applicable

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